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Panick et al.

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(54) **BINARY CONNECTOR FOR RECONSTITUTION**

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Related U.S. Application Data

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A61J 1/20 (2006.01)
A61J 1/14 (2023.01)

(52) **U.S. Cl.**
CPC ***A61J 1/2089*** (2013.01); ***A61J 1/1412*** (2013.01); ***A61J 1/201*** (2015.05); ***A61J 1/2055*** (2015.05)

(58) **Field of Classification Search**
CPC A61J 1/2089; A61J 1/1412; A61J 1/201; A61J 1/2055; A61J 1/2051; A61J 1/10; A61J 1/2013; A61J 1/20–2096; A61J 1/2037; A61J 1/1406; A61J 1/2058; F16K 5/02; F16K 5/0207; F16K 5/0214; F16K 5/0221; F16K 5/0228; F16K 5/0235; F16K 5/0242; F16K 5/025; F16K 5/0257; F16K 5/0264; F16K 5/0271; F16K 5/0278; F16K 5/0285; F16K 5/0292; F16K 5/04; F16K 5/0407; F16K 5/0414; F16K 5/0421; F16K 5/0428; F16K 5/0435; F16K 5/0442; F16K 5/045; F16K 5/0457; F16K 5/0464;
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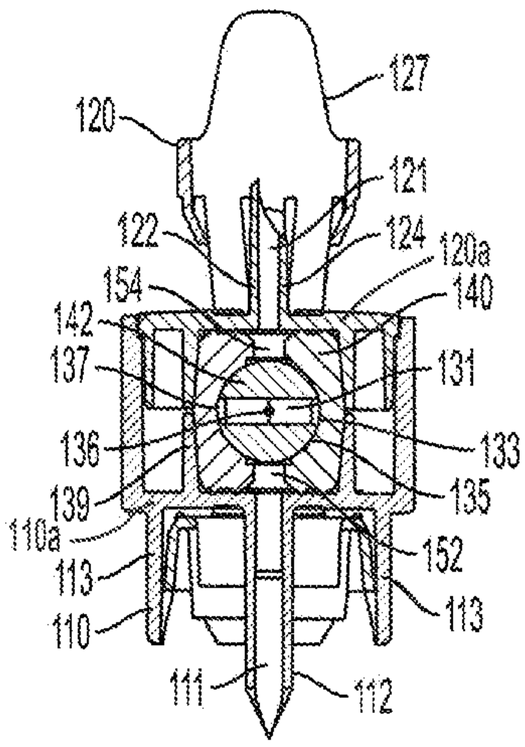
Primary Examiner — Kai H Weng
Assistant Examiner — Brandon W. Levy

(57) **ABSTRACT**

A connector is configured to connect a drug container with a solution container and permit contents of the drug container to be combined with the solution container. The connector has a connector body with a first coupling for fluid connection with the drug container. The first coupling defines a first fluid passage. The connector body also has a second coupling for fluid connection with the solution container. The second coupling defines a second fluid passage. A control valve has a movable valve body that defines a third fluid passage. The valve body is positionable relative to the connector body in a first position, in which the first fluid passage is sealed from the second fluid passage. The valve body is also positionable in a second position, in
(Continued)



which the first fluid passage is connected in fluid communication with the second fluid passage by the third fluid passage.

14 Claims, 9 Drawing Sheets

(58) **Field of Classification Search**
CPC F16K 5/0471; F16K 5/0478; F16K 5/0485; F16K 5/0492; A61M 39/223; A61M 5/162; A61M 2039/1072
See application file for complete search history.

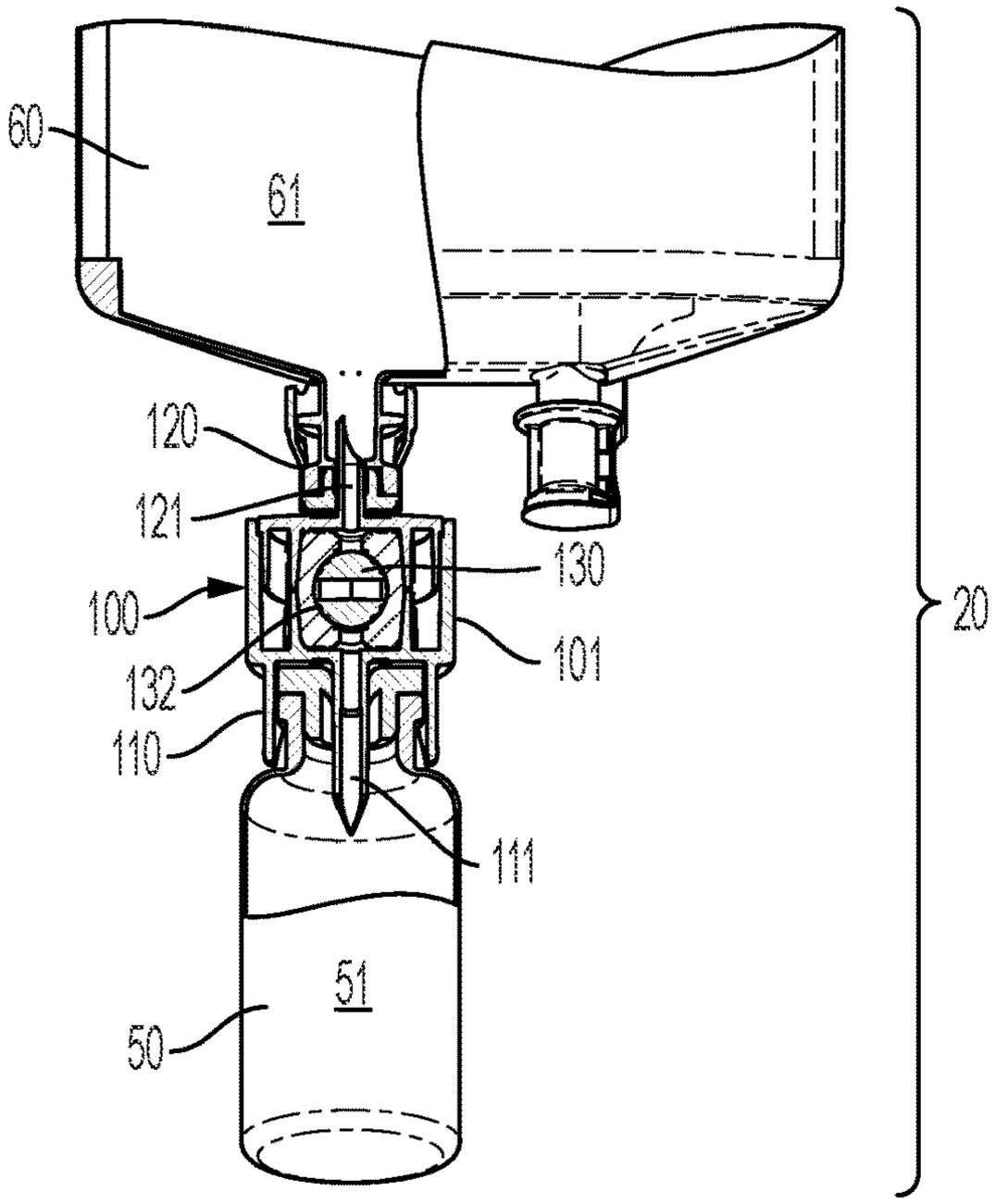

60
61
120
121
130
100
101
132
110
111
51
50
20

FIG. 1

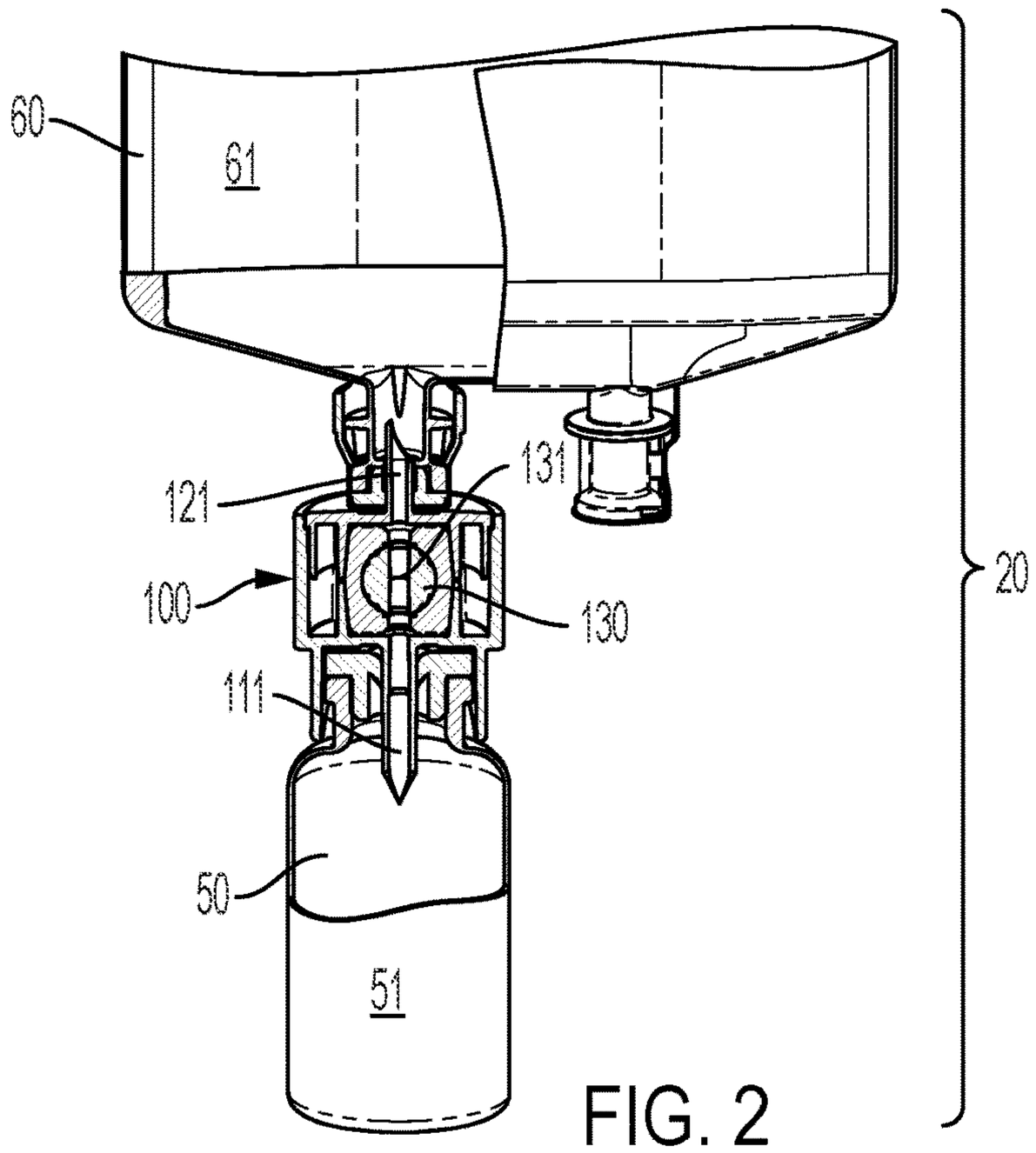

60
61
121
131
100
130
111
50
51
20

FIG. 2

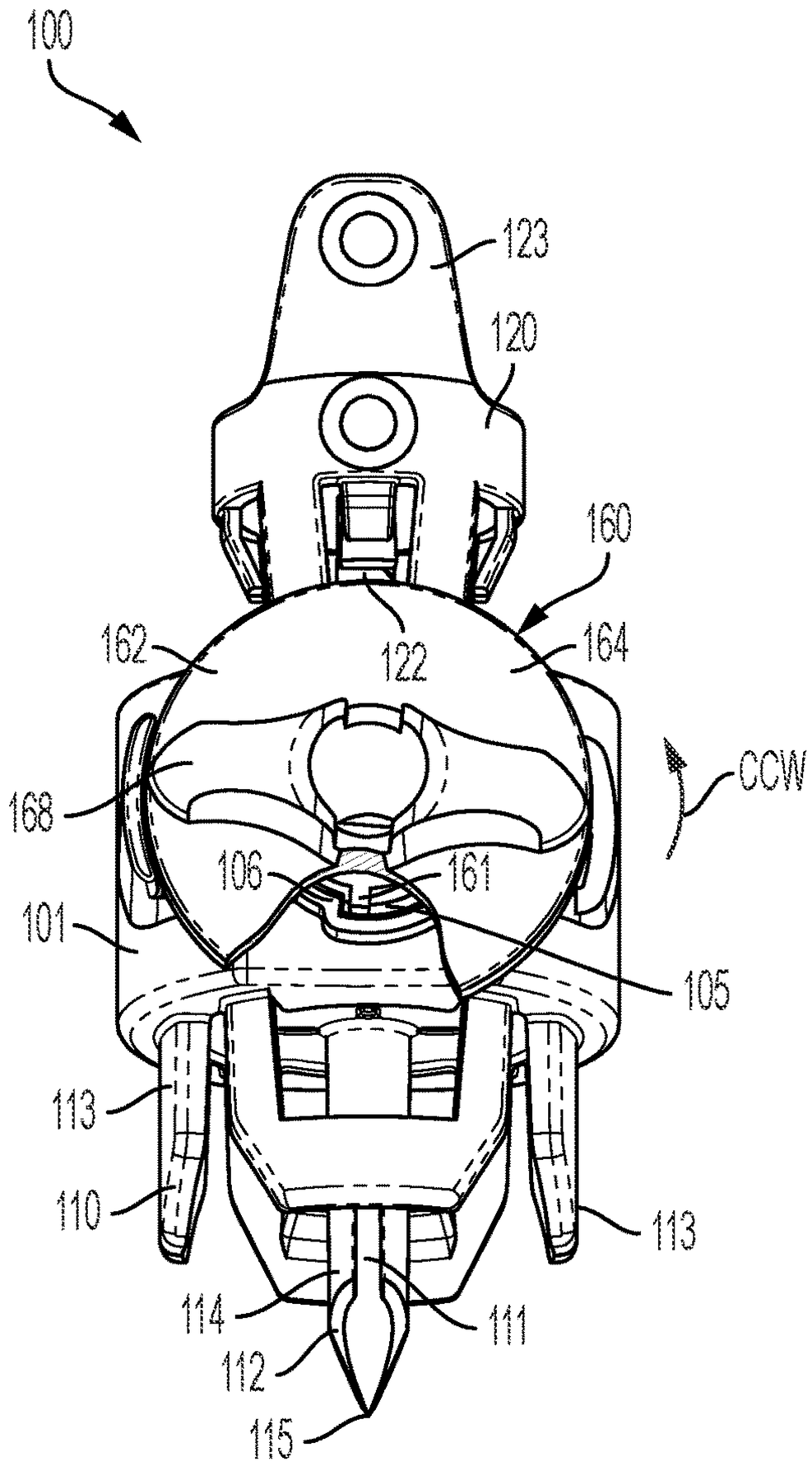

100
123
120
160
162
122
164
168
CCW
106
161
101
105
113
110
113
114
111
112
115

FIG. 3A

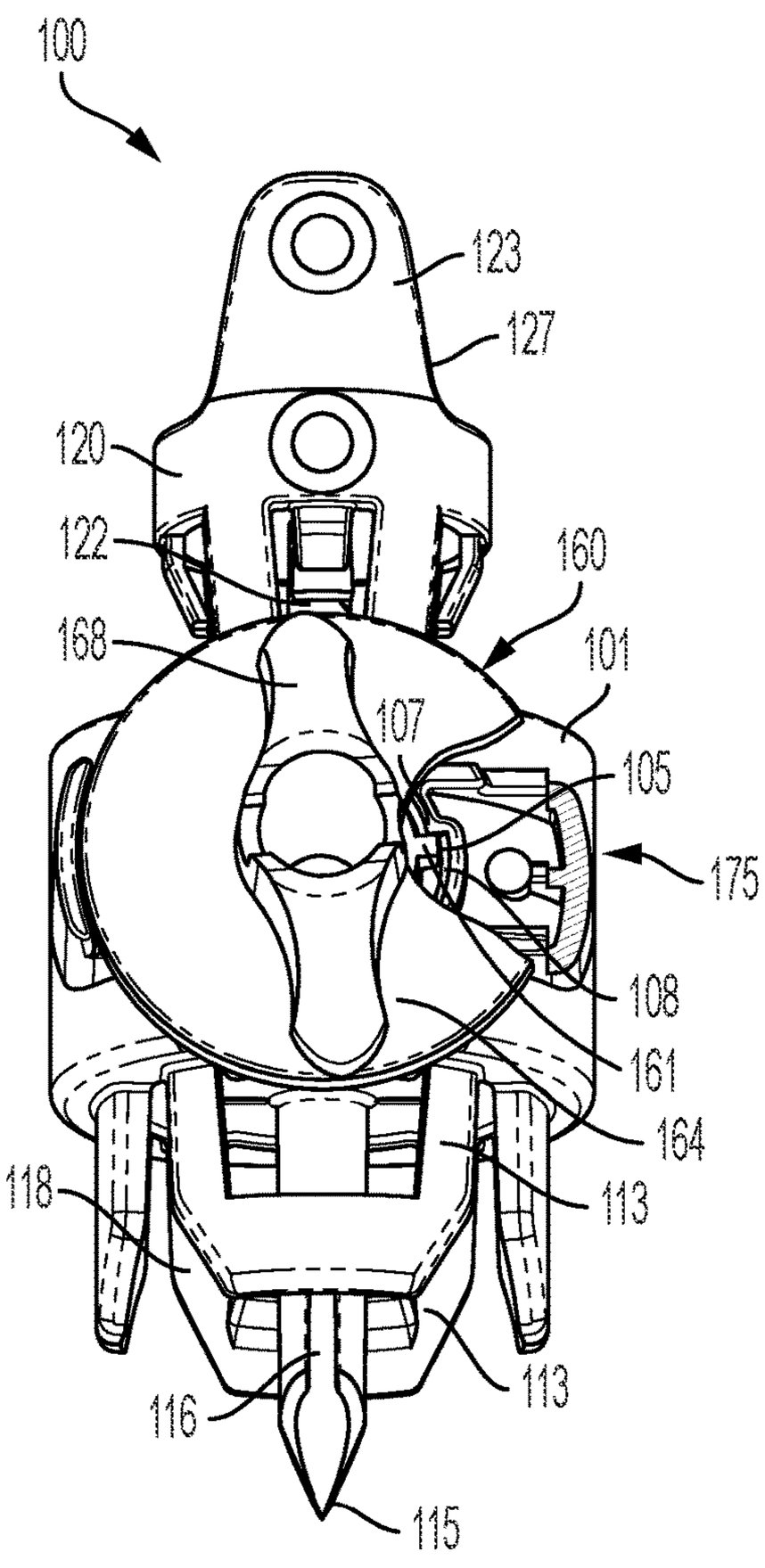

100
123
127
120
122
160
168
101
107
105
175
108
161
164
118
113
113
116
115

FIG. 3B

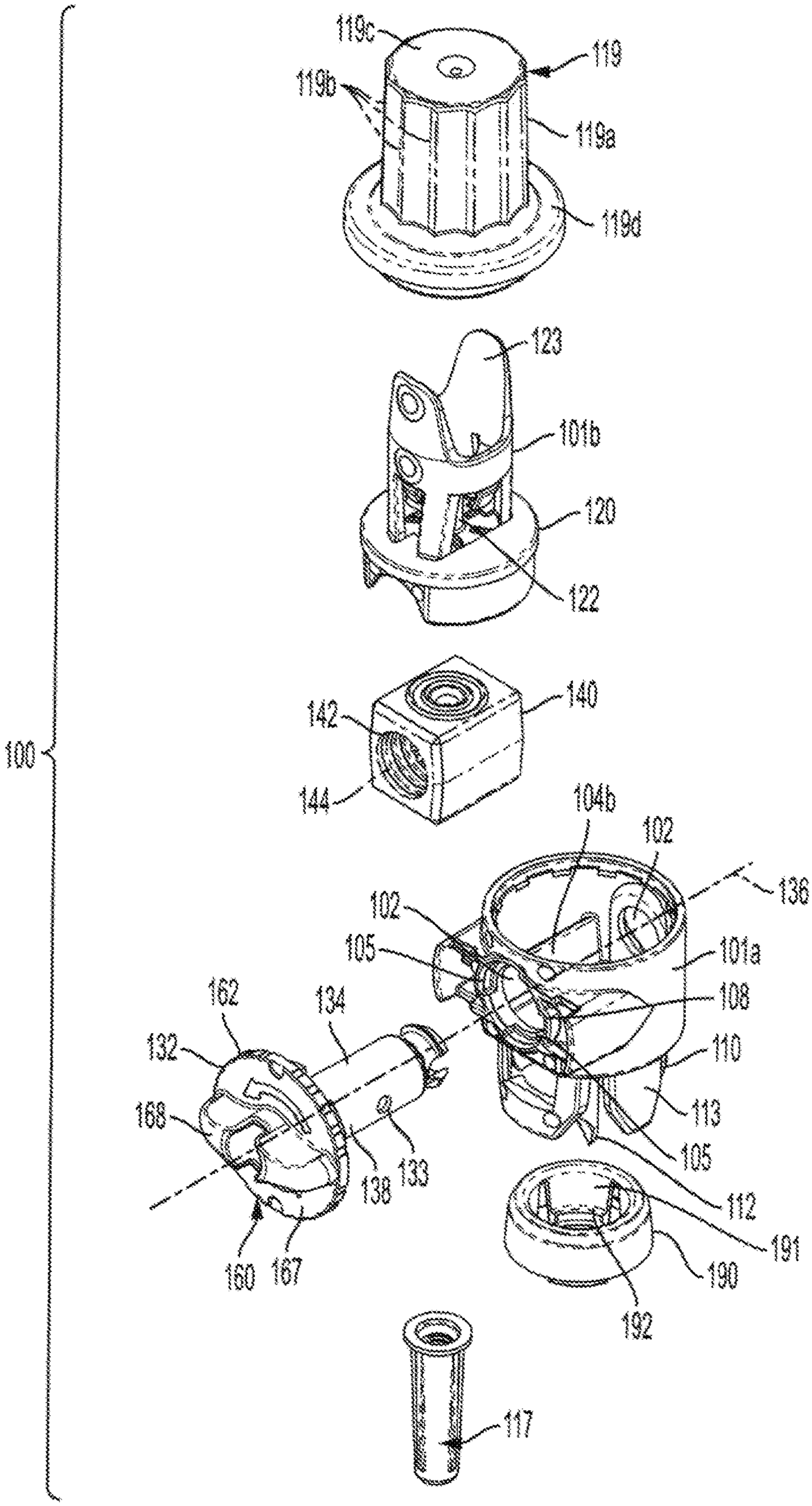

100
119c
119
119b
119a
119d
123
101b
120
122
140
142
144
104b
102
136
105
101a
108
162
134
110
132
113
168
105
112
191
138
133
190
160
167
192
117

FIG. 4

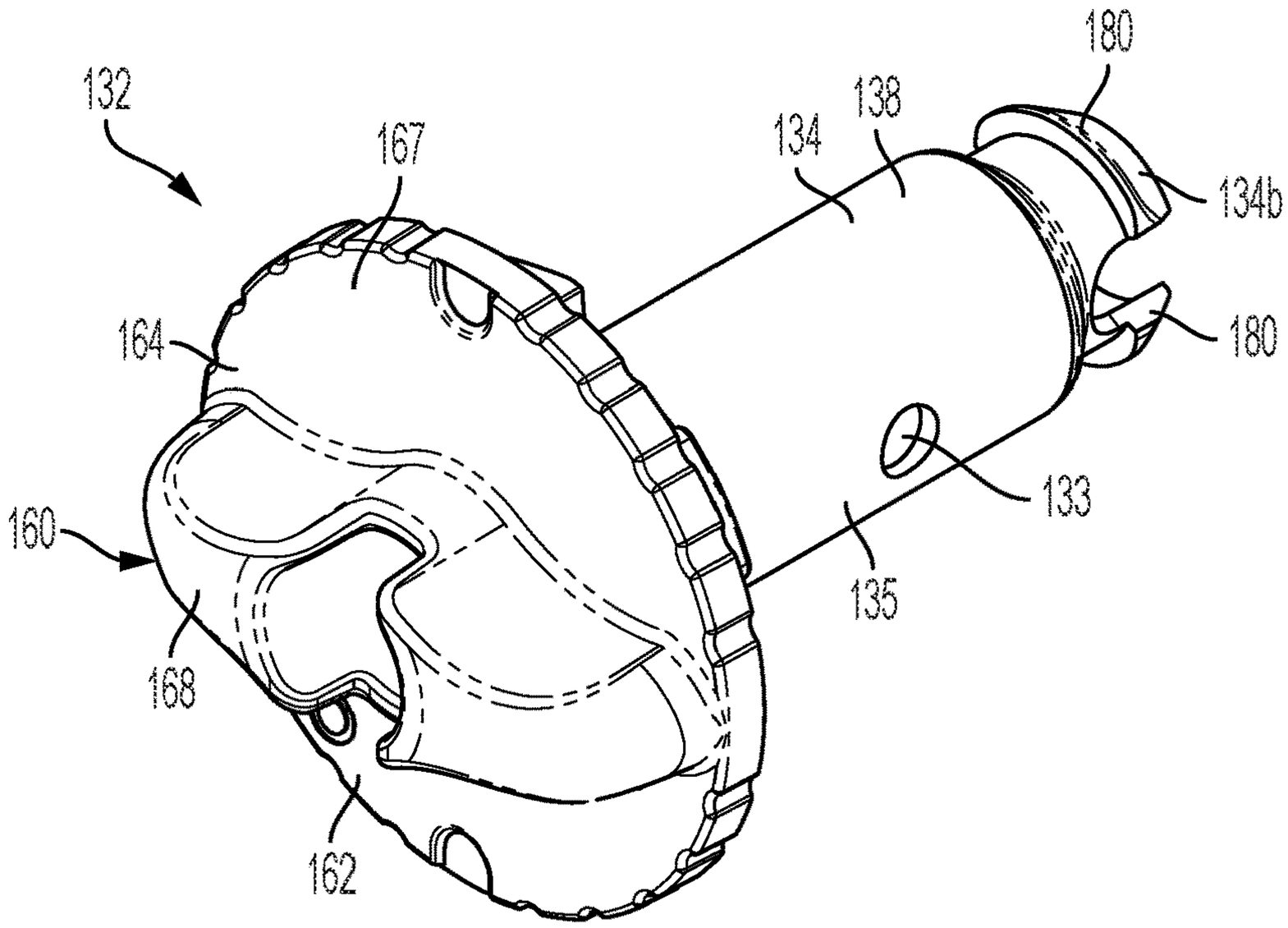

132
167
164
160
168
162
134
138
180
134b
180
133
135

FIG. 5

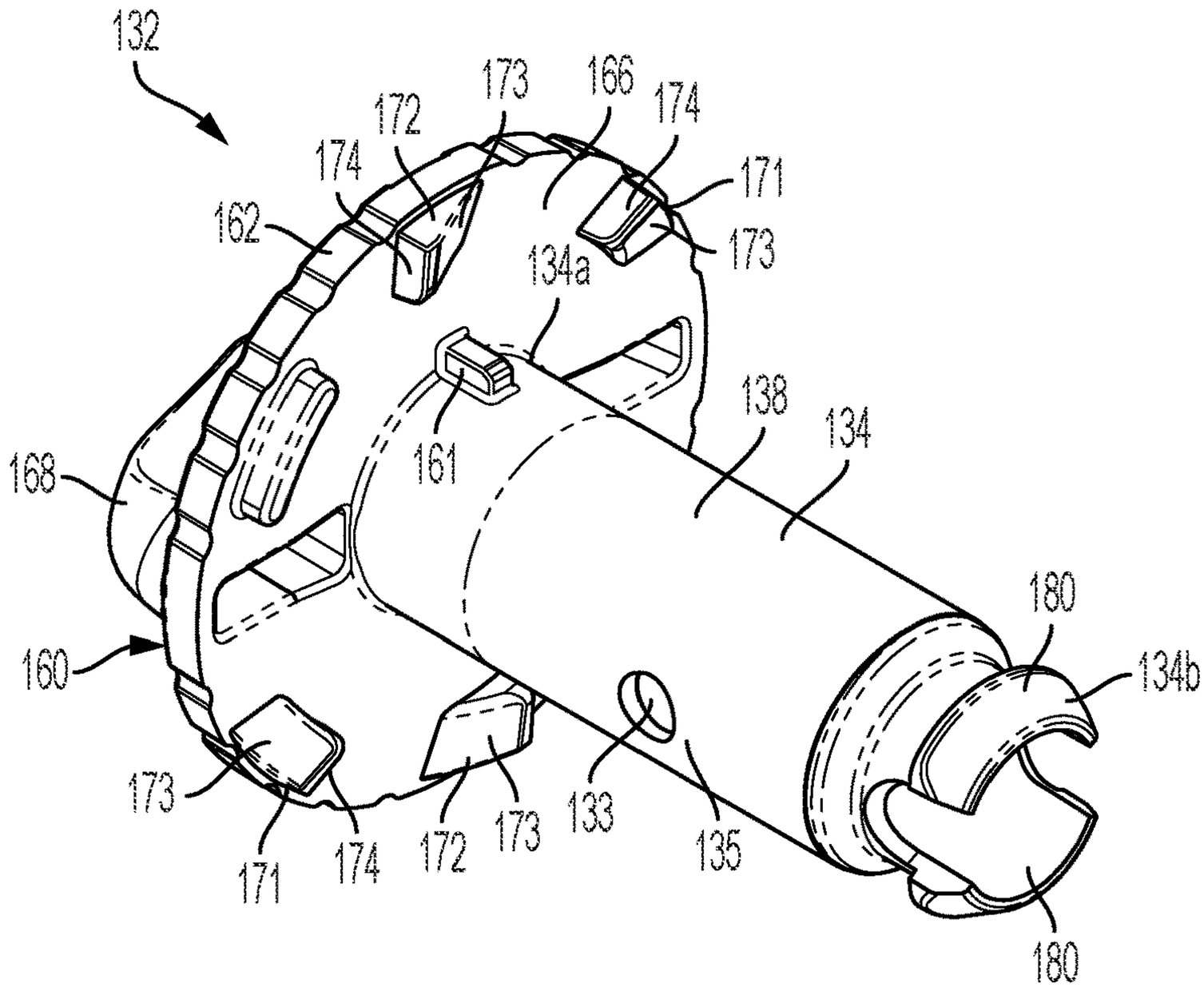

132
173
166
172
174
174
171
162
173
134a
161
138
134
168
180
160
134b
173
133
135
171
174
172
173
180

FIG. 6

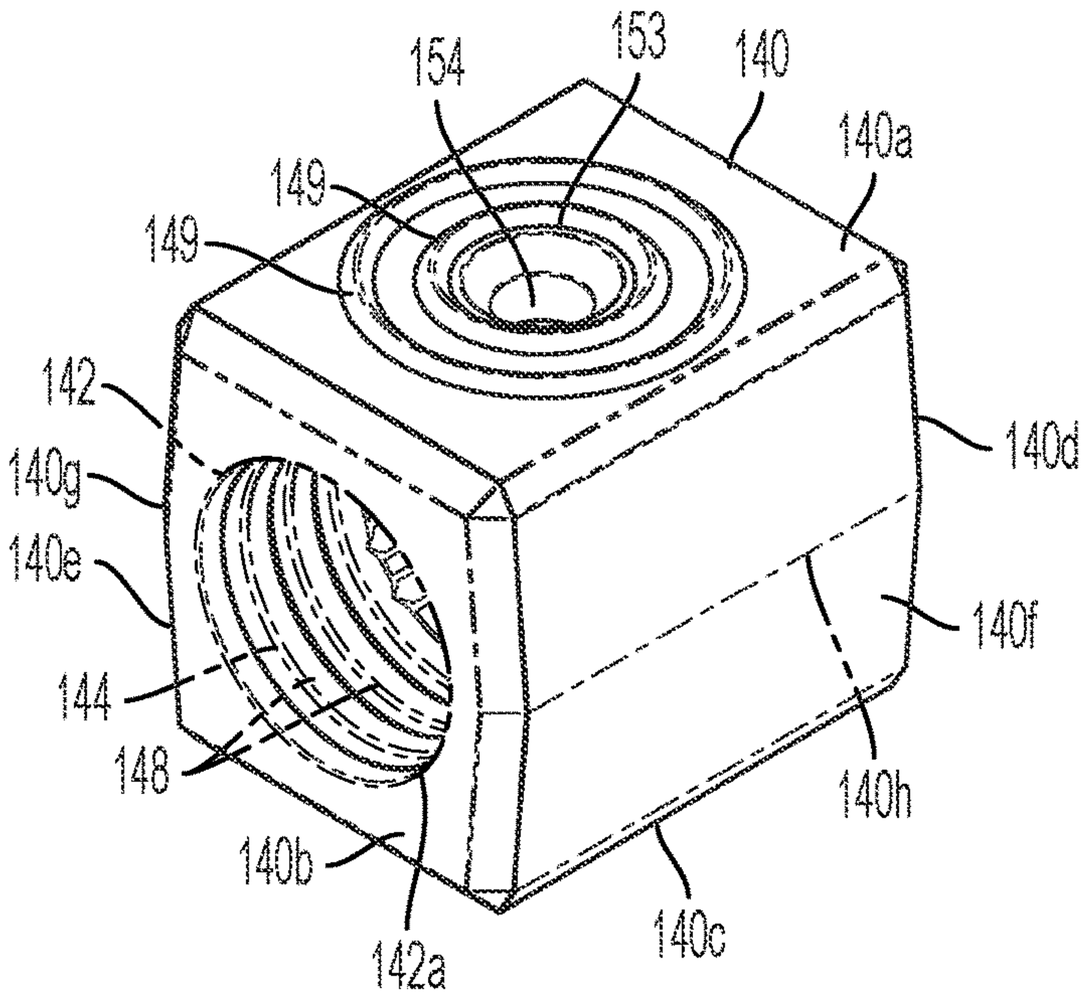


FIG. 7

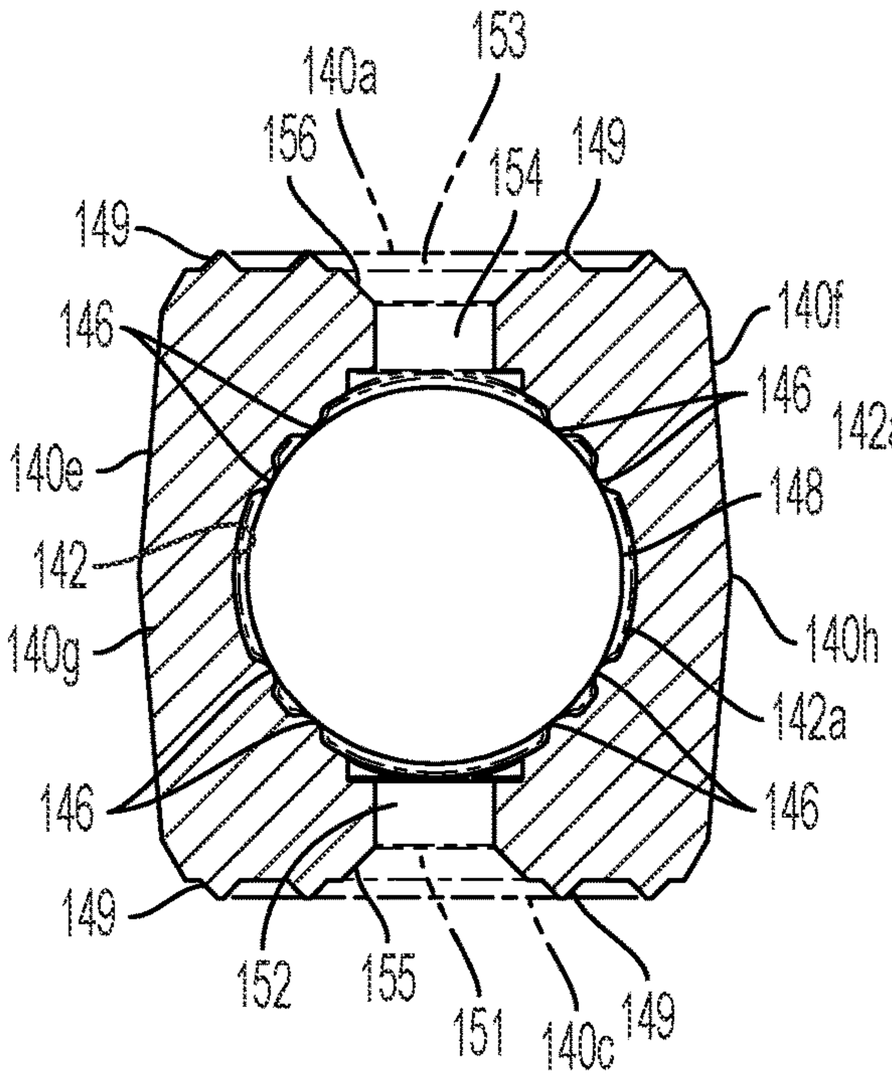


FIG. 8

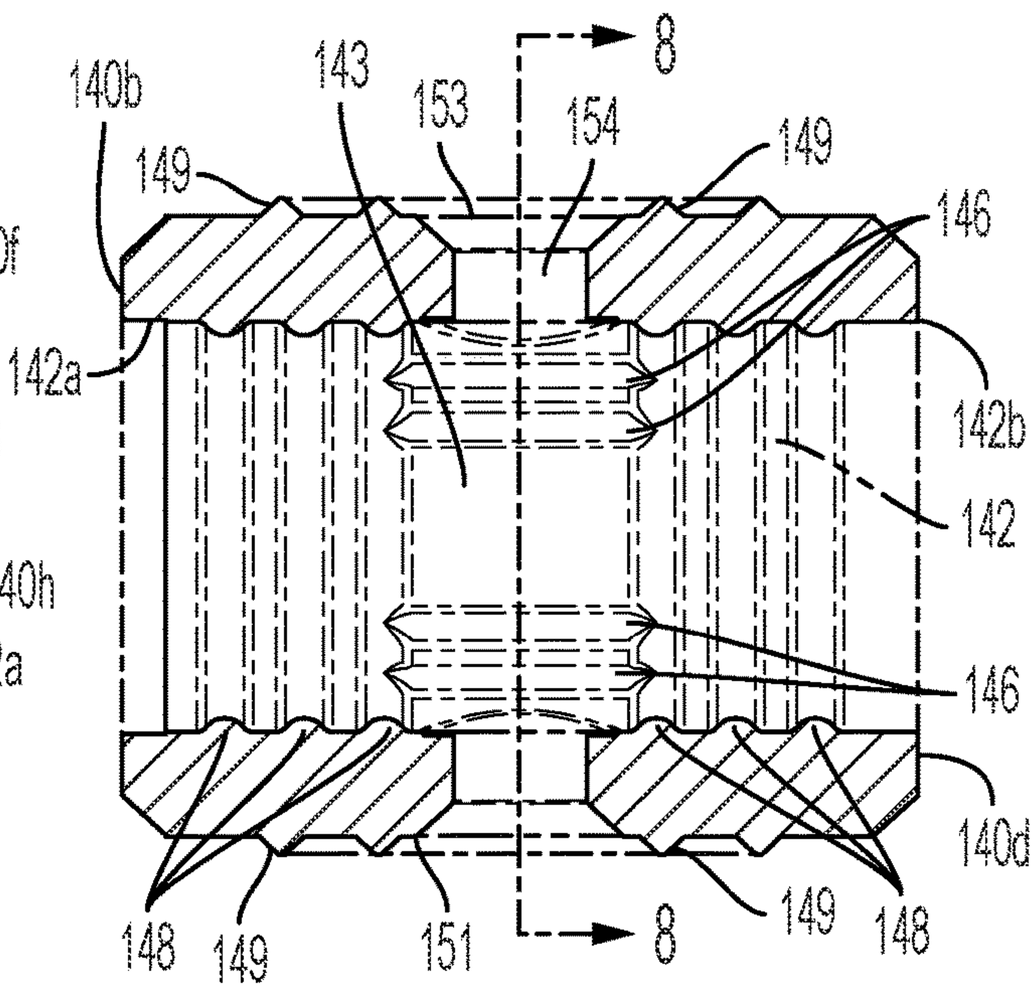


FIG. 9

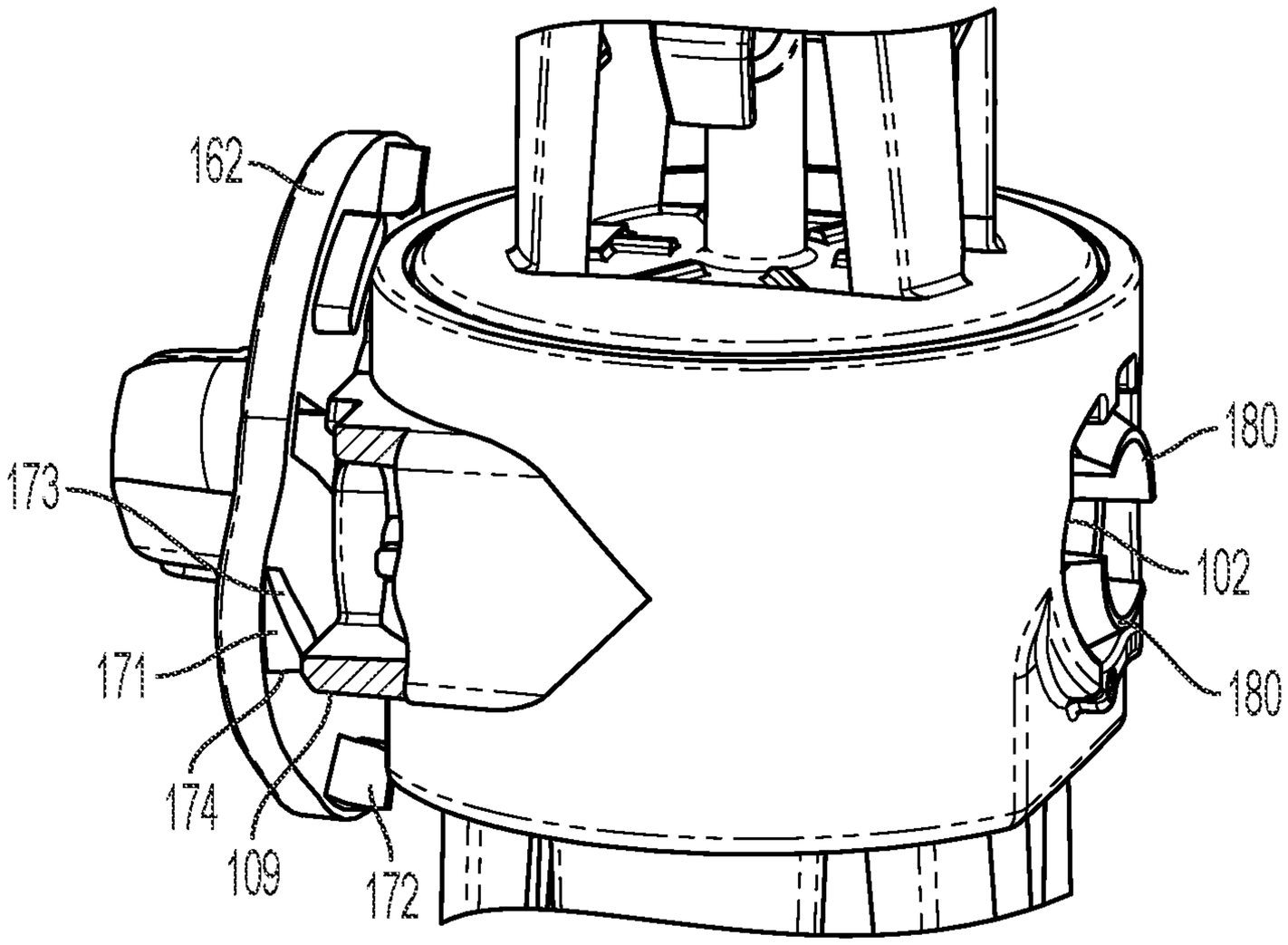


FIG. 10A

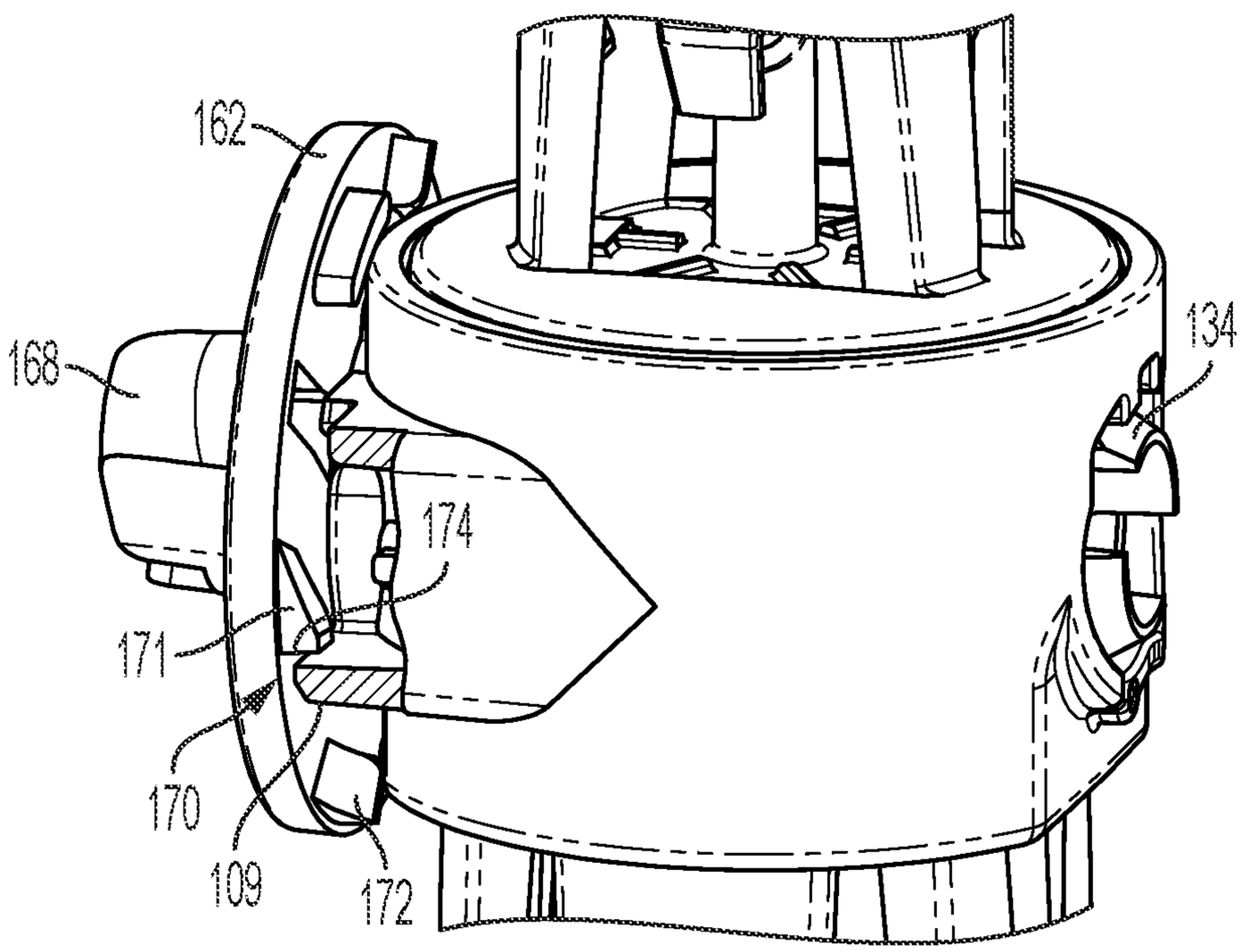


FIG. 10B

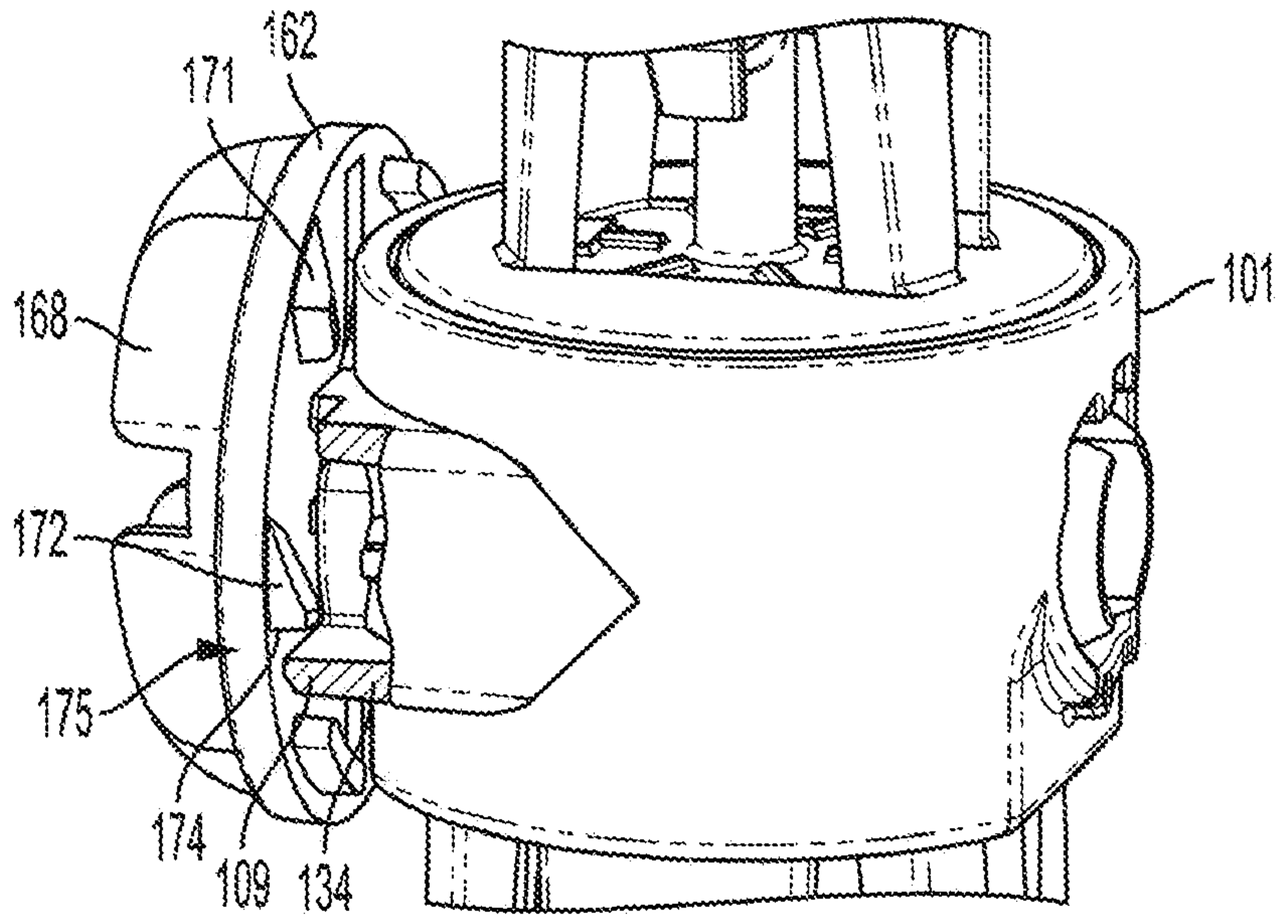


FIG. 10C

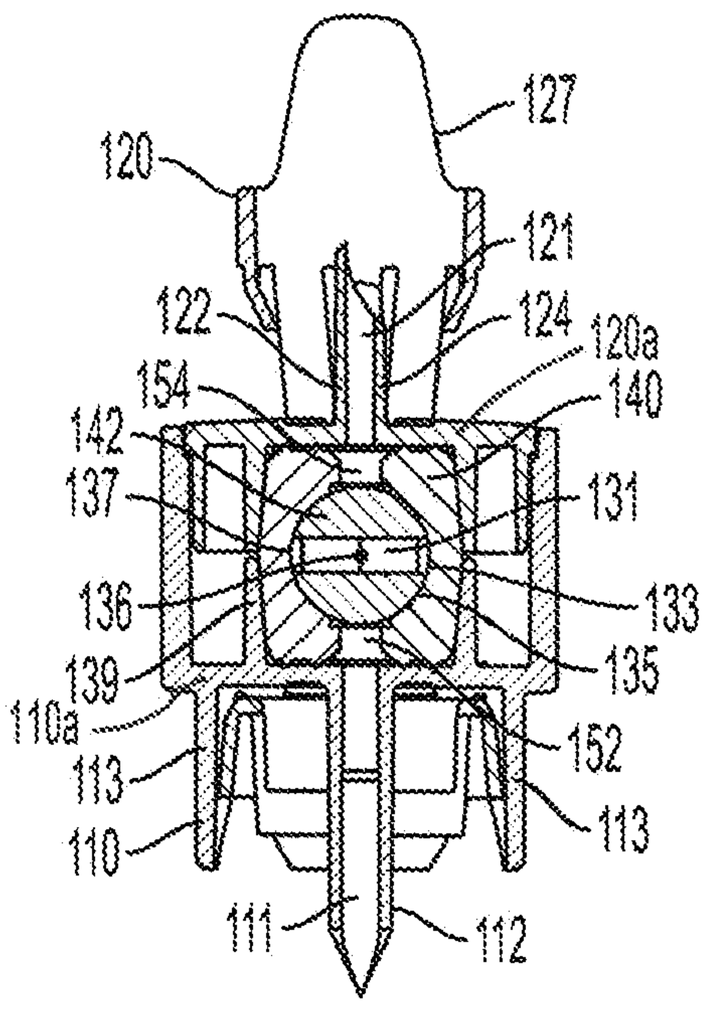


FIG. 11A

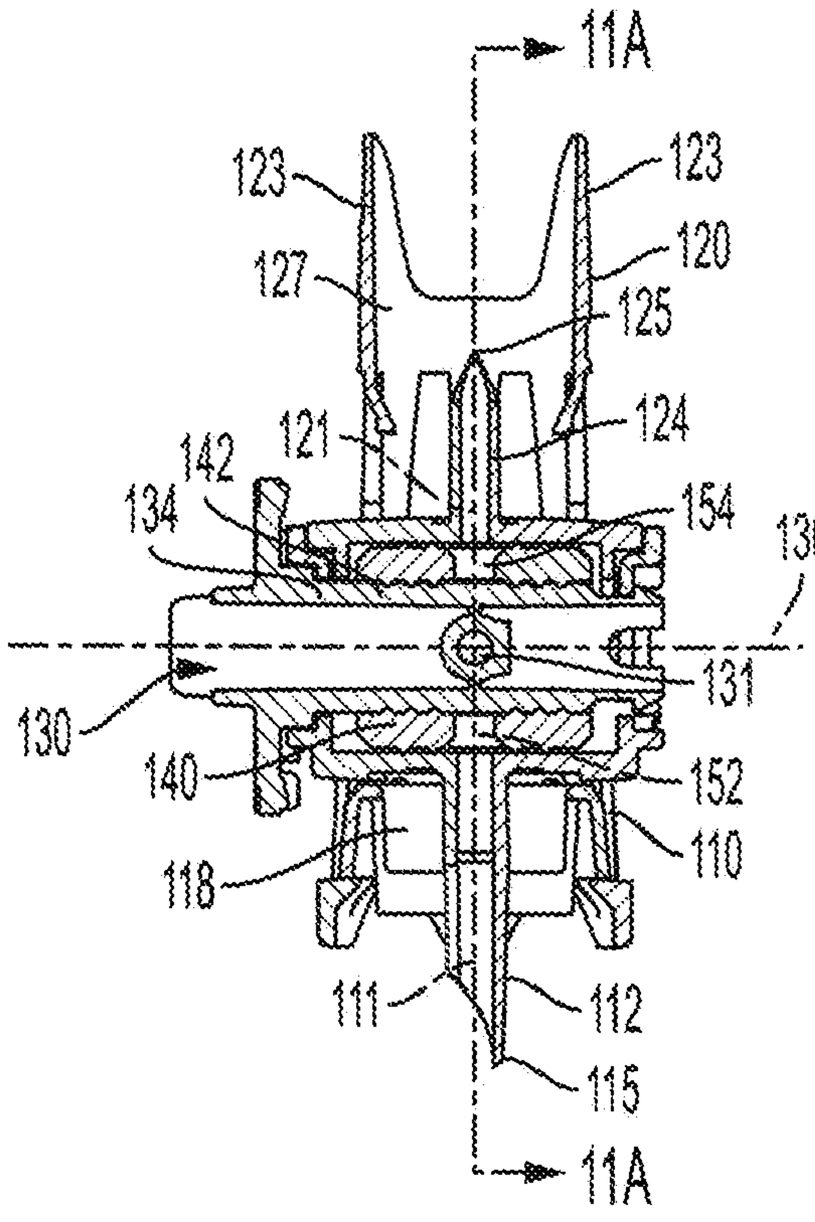


FIG. 11B

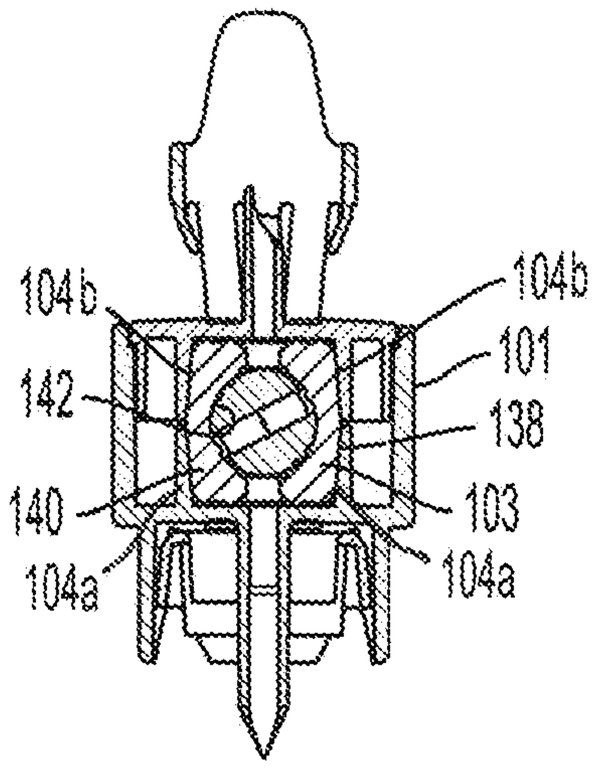


FIG. 12A

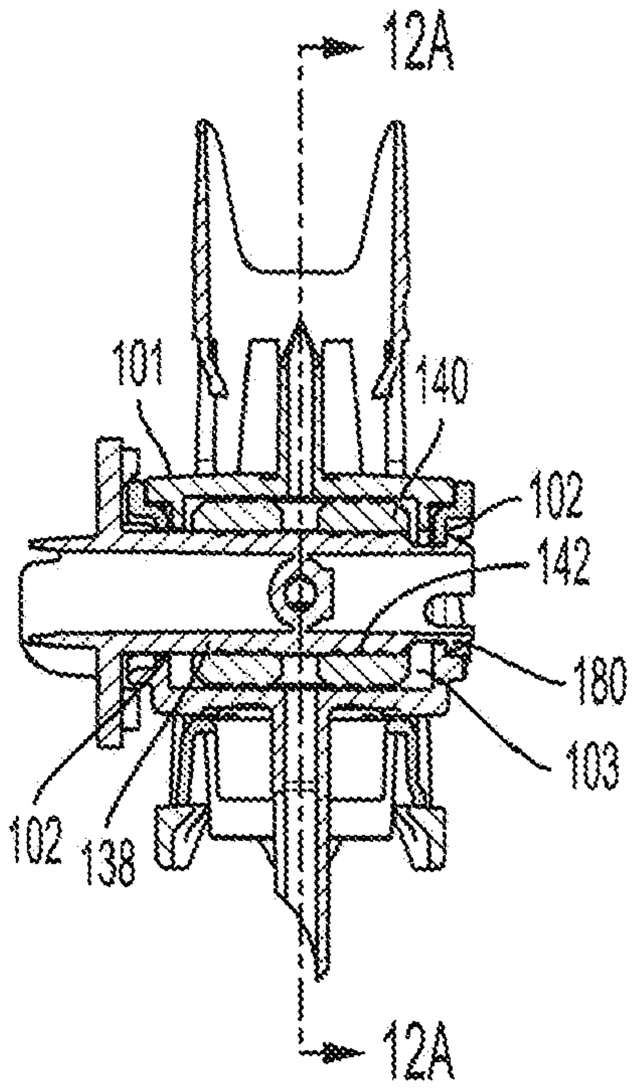


FIG. 12B

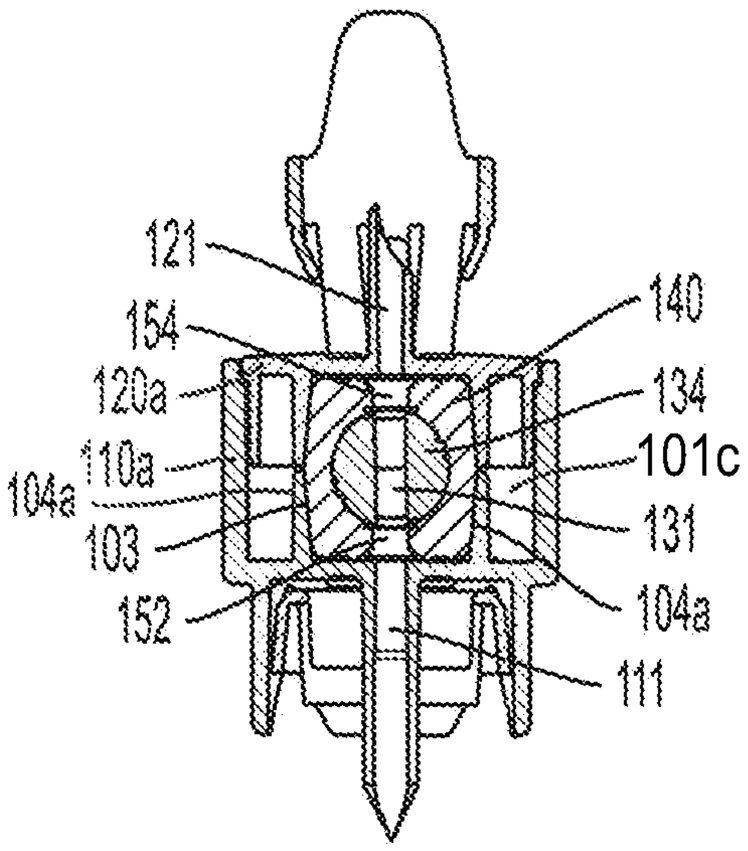


FIG. 13A

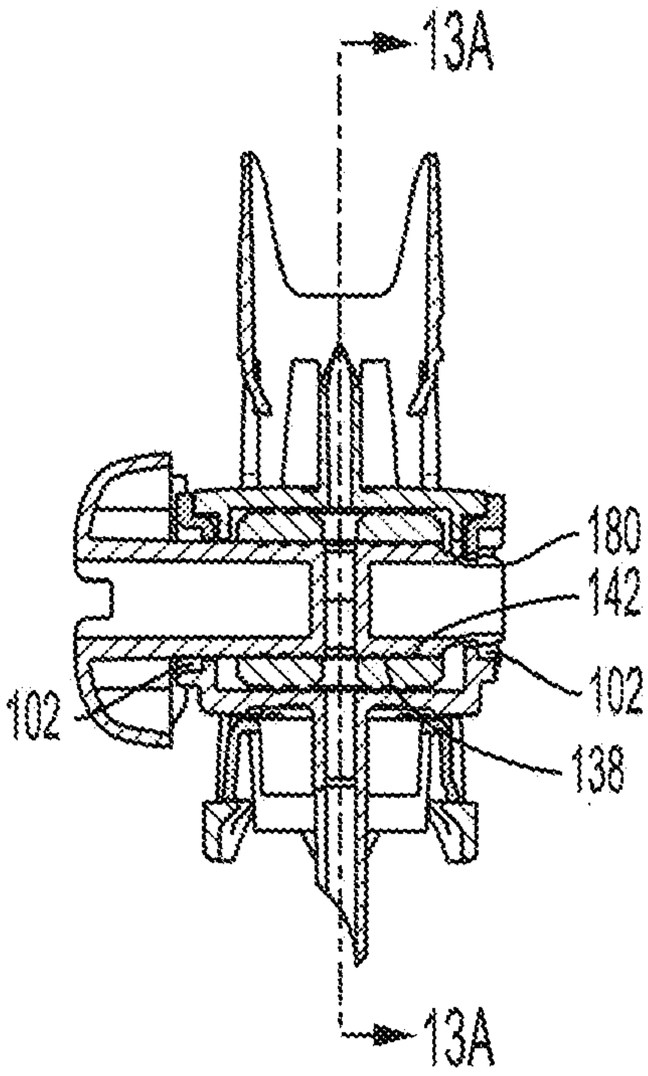


FIG. 13B

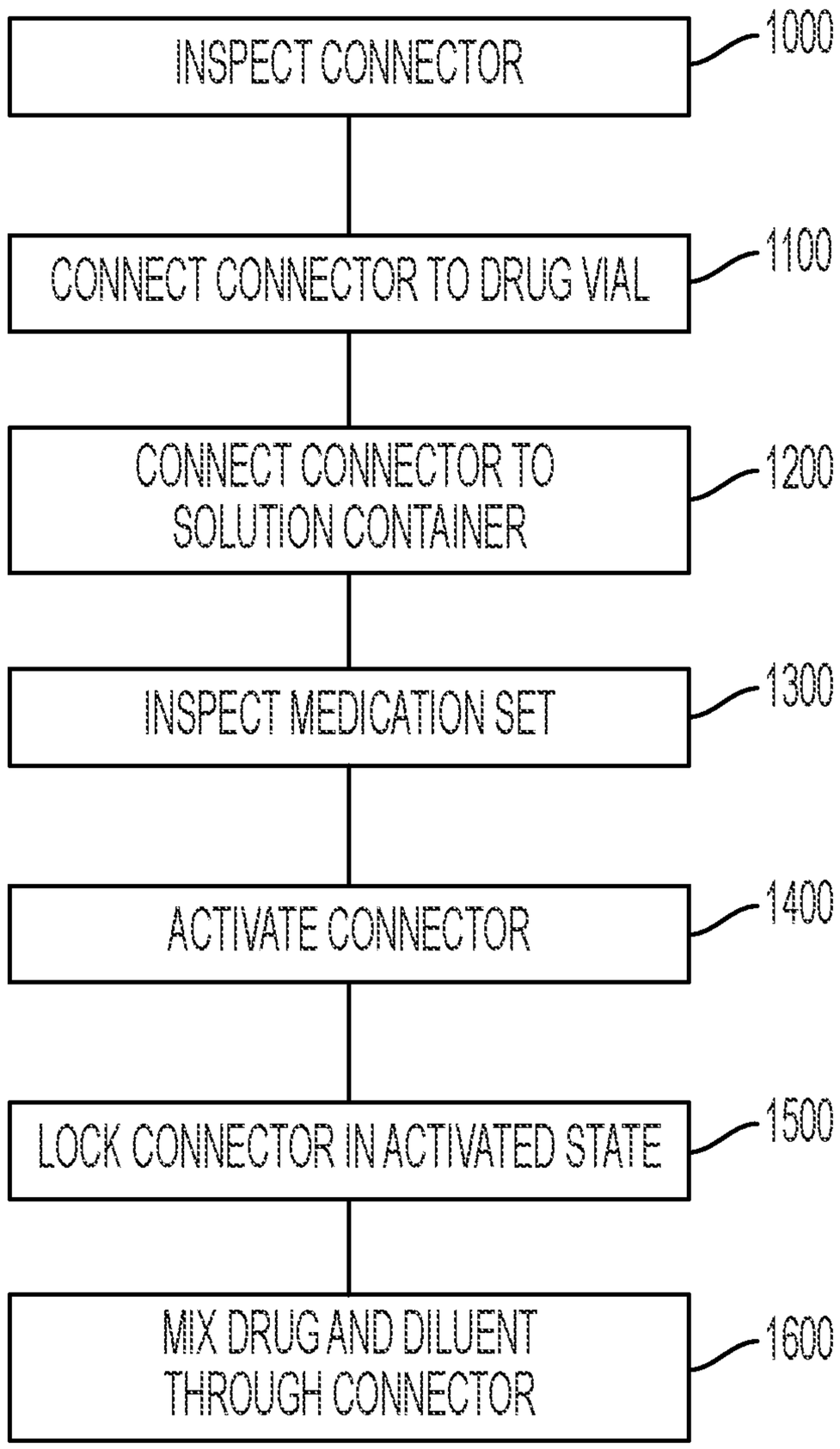

INSPECT CONNECTOR
1000
CONNECT CONNECTOR TO DRUG VIAL
1100
CONNECT CONNECTOR TO SOLUTION CONTAINER
1200
INSPECT MEDICATION SET
1300
ACTIVATE CONNECTOR
1400
LOCK CONNECTOR IN ACTIVATED STATE
1500
MIX DRUG AND DILUENT THROUGH CONNECTOR
1600

FIG. 14

BINARY CONNECTOR FOR RECONSTITUTION

FIELD

The present disclosure relates generally to the preparation and administration of intravenous solutions, and more specifically to a connector device for reconstituting a medication.

BACKGROUND

Some medications are manufactured in a concentrated liquid form that requires mixture with another liquid or "diluent" prior to being administered to a patient. Other medications are manufactured in a concentrated powder form that also requires mixture with a diluent prior to being administered to a patient. This mixing of concentrated medication with diluent, sometimes called "reconstitution", creates a drug solution or suspension that can be administered to a patient using an intravenous (IV) bag or container.

Medications and diluents are often stored separately. One reason for this is that drug solutions often have a relatively short shelf life after mixing. Keeping medications and diluents separate also allows a pharmacy to bulk prepare commonly used medications for an entire facility. Therefore, it is desirable to keep the medication and diluent separate until right before the drug solution is needed. Thorough mixing of medication with a diluent can take time, however. This can delay administration of the drug solution, costing a precious amount of time for patients who require urgent treatment.

To address these challenges, special IV containers, referred to herein as "solution containers", have been developed. A solution container has a port that allows concentrated medication to be transferred into the container and mixed with the diluent. This allows a drug solution to be prepared in the solution container a short time before the drug solution is needed.

Special adaptors have also been developed that allow concentrated medication stored in vials to be transferred into solution containers. These adaptors create fluid conduits between the drug vials and solution containers. A typical adapter has a first cannula or spike for connection to a port on a drug vial. The adapter also has a second cannula or spike for connection to a solution container. The vial spike can have a coring configuration designed to puncture a silicone septum on the drug vial and remove a piece of the septum or "plug" that remains lodged inside the spike. The plug blocks flow between the drug vial and adaptor, preventing flow between the adaptor and drug vial. In this plugged state, the adaptor interconnects the drug vial and solution container in a "ready-to-mix" assembly, but the drug and diluent are intended to remain separated.

When the drug solution is needed, the adaptor is designed in principle to be "activated". To activate the adaptor, the user squeezes the solution container, which creates fluid back pressure against the plug in the vial spike. This back pressure expels the plug from the vial spike into the vial, opening the passage between the adaptor and drug vial. The opened passage between the adaptor and drug vial allows diluent to enter the drug vial and mix with the drug to create a drug solution that flows back into the solution container.

Adaptors can simplify the preparation of drug solutions but have drawbacks that limit their effectiveness. As an initial concern, the correct use of adaptors is not intuitive for all users. For example, some users may incorrectly assume

that connecting an adaptor between a drug vial and solution container will immediately establish an open fluid passage that allows mixing of the drug with diluent. This can discourage users from pre-assembling the adaptor with the drug vial and solution bag ahead of time, out of fear that premature mixing will take place.

Other users may be unsure of how to activate the adaptor. This can result in users mishandling the solution bag, drug vial and/or anchor, resulting in accidental leakage or release of the drug or diluent from the system.

Another drawback is the absence of an indicator that informs the user whether the adaptor is activated. This can make users uncertain about whether the passage between the drug vial and solution container is open or closed. Such uncertainty can lead to doubt and concern about whether seepage or mixing has taken place during storage. Any mixture created during storage can expire and become unsafe for use. Therefore, if there is any doubt about activation, the user must discard the system.

Still another drawback is the possibility of accidental activation of the adaptor. Lack of care in handling and storing the assembled system can subject the system to compression loading, vibration, shock or other condition that causes the plug to dislodge from the vial spike. If the plug dislodges from the vial spike, and there is no seal between the connector and solution container, then the passage between the adaptor and drug vial will open, allowing mixing to take place.

Still another drawback is a lack of safety features that inform users that an adapter has been tampered with or used for a previous drug reconstitution. Adaptors should only be used once and then discarded. Unfortunately, it is possible to disconnect adaptors from solution containers after activation and restock them for reuse. Reuse of an adaptor can create a serious risk of infection or cross-contamination with a drug that was previously reconstituted with the adaptor.

The foregoing drawbacks illustrate the need for improved adaptors that are safer, more intuitive to use, and less prone to accidental or undesired mixing of drugs and diluents.

SUMMARY

The drawbacks of conventional adaptors are resolved in many respects with binary connectors in accordance with the present disclosure.

In one aspect of the disclosure, a connector can be configured for fluidly connecting a drug container with a solution container in a closed state, and for combining contents of the drug container and the solution container in an activated state.

In another aspect of the disclosure, the connector can include a connector body having a first coupling for fluid connection with the drug container. The first coupling can define a first fluid passage.

In another aspect of the disclosure, the connector can include a second coupling for fluid connection with the solution container. The second coupling can define a second fluid passage.

In another aspect of the disclosure, the connector can have a control valve with a movable valve body. The valve body can define a third fluid passage.

In another aspect of the disclosure, the valve body can be positionable relative to the connector body in a first position, in which the first fluid passage is sealed from the second fluid passage to place the connector in the closed state.

In another aspect of the disclosure, the valve body can be positionable relative to the connector body in a second

position, in which the first fluid passage is connected in fluid communication with the second fluid passage by the third fluid passage to place the connector in the activated state.

In another aspect of the disclosure, the first fluid passage can extend parallel to the second fluid passage.

In another aspect of the disclosure, the first coupling can include a first piercing member having a first hollow body defining the first fluid passage.

In another aspect of the disclosure, the second coupling can include a second piercing member having a second hollow body defining the second fluid passage.

In another aspect of the disclosure, the valve body can include a shaft extending into the connector body, the shaft being rotatable relative to the connector body on a control axis.

In another aspect of the disclosure, the third fluid passage can extend through the shaft transversely to the control axis.

In another aspect of the disclosure, the third fluid passage can define a first opening on a first side of the shaft and a second opening on a second side of the shaft.

In another aspect of the disclosure, the first opening can be diametrically opposite the second opening on the shaft.

In another aspect of the disclosure, the shaft can be cylindrical and include a cylindrical shaft surface.

In another aspect of the disclosure, the control valve can include a seal body that surrounds the shaft surface.

In another aspect of the disclosure, the seal body can define a seal body passage having a passage wall that slidingly engages the shaft surface.

In another aspect of the disclosure, the seal body passage can include a first passage end, a second passage end, and an inner diameter that varies between the first passage end and second passage end.

In another aspect of the disclosure, the seal body passage can form one or more sections of reduced diameter configured to engage, wipe and form one or more seals with the cylindrical shaft surface.

In another aspect of the disclosure, the passage wall can include at least one annular seal that forms a seal interface between the seal body and the shaft.

In another aspect of the disclosure, the seal body can define a first aperture that forms a first conduit between the seal body passage and the first flow passage, and a second aperture that forms a second conduit between the seal body passage and the second flow passage.

In another aspect of the disclosure, the first conduit and second conduit can be axially aligned with one another and located on opposite sides of the seal body passage.

In another aspect of the disclosure, the third fluid passage can be aligned with the first conduit and the second conduit when the connector is in the activated state.

In another aspect of the disclosure, the third fluid passage can be rotated out of alignment with at least one of the first conduit and the second conduit when the connector is in the closed state.

In another aspect of the disclosure, the seal body can include an exterior surface having at least one sealing rib around the first aperture and at least one sealing rib around the second aperture.

In another aspect of the disclosure, the control valve can include a control handle attached to the shaft.

In another aspect of the disclosure, the control handle can be rotatable relative to the connector body to rotate the shaft about the control axis.

In another aspect of the disclosure, the control handle can be rotated to a first orientation in which the valve body is in the first position to place the connector in the closed state.

In another aspect of the disclosure, the control handle can be rotated to a second orientation in which the valve body is in the second position to place the connector in the activated state.

In another aspect of the disclosure, the control handle can include a lock that prevents rotation of the valve body from the second position to the first position.

In another aspect of the disclosure, the lock can include a first locking element on the control handle and a second locking element on the connector body.

In another aspect of the disclosure, the first locking element can be configured to engage the second locking element when the control handle is rotated to the second orientation.

In another aspect of the disclosure, the first locking element can include at least one ratchet tooth, and the second locking element can include a ledge.

In another aspect of the disclosure, the control handle can include a first rotation limiter and the connector body can include a second rotation limiter.

In another aspect of the disclosure, the first rotation limiter can be configured to abut the second rotation limiter when the control handle is rotated to the second orientation to prevent the control handle from rotating past the second orientation.

In another aspect of the disclosure, the first coupling can include a plurality of flexible tabs arranged in a circular arrangement around the first fluid passage.

In another aspect of the disclosure, the plurality of flexible tabs can define a first socket sized to receive the drug container.

In another aspect of the disclosure, the first coupling can include an adapter ring detachably connected to the first socket.

In another aspect of the disclosure, the adapter ring can be sized to receive an alternate drug container having a different configuration than the drug container.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

The foregoing summary and the following detailed description will be better understood in conjunction with non-limiting examples shown in the drawing figures, of which:

FIG. **1** is a front cross sectional view of a connector according to one example of the present disclosure, the connector shown attached to a drug vial and solution container in a first operative state;

FIG. **2** is another front cross sectional view of the connector of FIG. **1**, shown in a second operative state;

FIG. **3**A is a front view of the connector of FIG. **1**, with a section broken away to show interior elements of the connector in the first operative state;

FIG. **3**B is a front view of the connector of FIG. **1**, with a section broken away to show interior elements of the connector in the second operative state;

FIG. **4** is an exploded perspective view of the connector of FIG. **1** with additional accessories;

FIG. **5** is an enlarged perspective view of a valve body of the connector of FIG. **1**;

FIG. **6** is another enlarged perspective view of the valve body of the connector of FIG. **1**;

FIG. **7** is an enlarged perspective view of a seal body of the connector of FIG. **1**;

FIG. **8** is a first cross sectional view of the seal body of the connector of FIG. **1**;

FIG. **9** is a second cross sectional view of the seal body of the connector of FIG. **1**;

FIG. **10**A is a truncated perspective view of the connector of FIG. **1**, with a dial rotated to a first position;

FIG. **10**B is a truncated perspective view of the connector of FIG. **1**, with the dial rotated to a second position;

FIG. **10**C is a truncated perspective view of the connector of FIG. **1**, with the dial rotated to a third position;

FIG. **11**A is front cross sectional view of the connector of FIG. **1**, with the valve body positioned in a first position;

FIG. **11**B is a side cross sectional view of the connector of FIG. **1**, with the valve body positioned in the first position;

FIG. **12**A is front cross sectional view of the connector of FIG. **1**, with the valve body positioned in a second position;

FIG. **12**B is a side cross sectional view of the connector of FIG. **1**, with the valve body positioned in the second position;

FIG. **13**A is front cross sectional view of the connector of FIG. **1**, with the valve body positioned in a third position;

FIG. **13**B is a side cross sectional view of the connector of FIG. **1**, with the valve body positioned in the third position; and

FIG. **14** is a diagram illustrating a method of operating the connector of FIG. **1** according to the present disclosure.

DETAILED DESCRIPTION

Referring to the drawing figures generally, and FIGS. **1** and **2** in particular, a connector **100** for connecting a drug vial **50** with a solution container **60** is shown according to one example. Connector **100** has a connector body **101** with a first coupling **110** and a second coupling **120**. First coupling **110** is connected to drug vial **50**, which contains a drug **51**. Second coupling **120** is connected to solution container **60**, which contains a diluent **61**. In this arrangement, connector **100** connects drug vial **50** and solution container **60** to create an assembly or set **20** for reconstituting drug **51**.

Set **20** provides a convenient way to store drug vial **50** and solution container **60** in a pre-connected, "ready-to-mix" assembly. Drug vial **50** and solution container **60** are not stored in a fluidly connected state, however. Instead, drug vial **50** and solution container **60** are stored in a sealed off arrangement, in which connector **100** prevents drug **51** from combining with diluent **61**, and vice versa. This sealed off arrangement is established independent of any plug that may or may not be created in either coupling. Fluid communication between drug vial **50** and solution container **60** is established only when a user activates the connector **100** to allow mixing to take place. Once connector **100** is activated, various indicators on the device inform the user that the connector is activated. Connector **100** remains locked in the activated state after activation, preventing the connector from being reused.

FIG. **1** provides a cross sectional view of connector **100**, and partial cross section views of drug vial **50** and solution container **60**. Connector **100** is shown in a "closed state", in which the connector interconnects drug vial **50** and solution container **60** in a sealed arrangement that prevents drug **51** from mixing with diluent **61**. The transfer of fluid between drug vial **50** and solution container **60** is prevented by a control valve **130**, which is shown in a closed condition.

FIG. **2** provides another cross sectional view of connector **100**, and partial cross sectional views of drug vial **50** and solution container **60**. Connector **100** is shown in the activated state, in which the connector interconnects drug vial **50** and solution container **60** in an unsealed arrangement that permits drug **51** to mix with diluent **61**. The transfer of fluid between drug vial **50** and solution container **60** is permitted by control valve **130**, which is shown in an open condition.

Couplings according to the present disclosure can include fluid passages in various shapes and configurations that allow mixing of drugs with diluents. Each fluid passage can be made up of a single straight segment, a single curved segment, multiple straight segments, multiple curved segments, or a combination of straight and curved segments. In addition, each fluid passage can have a uniform cross section along its entire length, or one or more changes in cross section.

In the present example, with reference to FIGS. **11**A, **12**A and **13**A, first coupling **110** has a first outer wall **110***a* that defines a first fluid passage **111** and a pair of first chamber walls **104***a*. First fluid passage **111** has a single linear segment and a uniform cross section along its length. Likewise, second coupling **120** has a second outer wall **120***a* that defines a second fluid passage **121** and a pair of second chamber walls **104***b*. Second fluid passage has a single linear segment and a uniform cross section along its length. First and second fluid passages **111**, **121** are axially aligned to one another. The linear and uniform profiles of first and second fluid **5** passages **111**, **121** provide minimal transitions to allow transfer of fluid smoothly through connector **100**.

Control valve **130** includes a valve body **132** defining a third fluid passage **131**. Third fluid passage **131** extends through valve body **132**, and can be aligned with first fluid passage **111** and second fluid passage **121** to allow fluid to flow between drug vial **50** and solution container **60**. The orientation of third fluid passage **131** relative to first and second flow passages **111**, **121** is dictated by the orientation of valve body **132** relative to connector body **101**.

Valve body **132** is positionable relative to connector body **101** in a first position, shown in FIG. **1**. In this position, third fluid passage **131** is not aligned with first and second fluid passages **111**, **121**. First fluid passage **111** is sealed from second fluid passage **121** by a number of sealed interfaces, as will be explained. Thus, connector **100** physically connects drug vial **50** and solution bag **60**, but does not provide fluid communication between them.

Valve body **132** is movable from the first position to the second position, shown in FIG. **2**. In this position, third fluid passage **131** is axially aligned with first and second fluid passages **111**, **121**. Therefore, third fluid passage **131** fluidly connects first fluid passage **111** with second fluid passage **121**, and vice versa. As such, connector **100** physically connects drug vial **50** and solution bag **60**, and provides fluid communication between them.

Connectors according to the present disclosure can feature any suitable coupling that allows the connector body to establish a fluid connection with fluid containers. Suitable couplings can include but are not limited to various types of needles, cannulas, spikes, and other tubular or non-tubular connectors that pierce or plug into an access port, stopper or other access point on a fluid container. Suitable couplings can also include various types of port structures, stoppers or other access points configured to receive needles, cannulas, spikes, and other tubular or non-tubular connectors that pierce or plug into them. Piercing connectors according to the present disclosure can have a coring configuration to remove a plug from a stopper or septum that remains in the connector to temporarily block flow through the fluid passage. Alternatively, couplings according to the present dis-

closure can utilize non-coring connectors. Thus, connectors according to the present disclosure do not require plugs to control activation.

Referring to FIGS. **3**A, **3**B, **11**A and **11**B, first coupling **110** includes a first piercing member in the form of a vial spike **112**. Vial spike **112** has a first hollow body **114** that defines the first fluid passage **111**. First hollow body **114** also has a pointed tip **115** and defines a longitudinal slot **116** on one side. First coupling **110** further includes four flexible tabs **113** that surround vial spike **112**. Tabs **113** collectively form a socket **118** configured to receive the neck portion of drug vial **50**, as shown in FIGS. **1** and **2**. Tabs **113** firmly latch around drug vial **50** to limit lateral movement of the drug vial after it is connected to first coupling **110**.

Connectors according to the present disclosure can be configured to attach to vials of a certain type. For example, the connectors can have sockets designed to only accommodate vials of a selected size. These connectors can include adaptors that allow the connectors to attach to vials that do not have the selected size. In the present example, socket **118** is configured to attach to a 20 mm vial. An optional adaptor **190**, shown in FIG. **4**, can be inserted into socket **118** to allow connector **100** to attach to a 13 mm vial. Adaptor **190** has a plurality of flexible tabs **191** forming a socket **192** that is a smaller version of socket **118** and sized proportional to a 13 mm vial. Additional adaptors having other sizes can be provided with connector **100** that allow the connector to attach to vials of other sizes.

Referring again to FIGS. **3**A, **3**B, **11**A and **11**B, second coupling **120** includes a second piercing member in the form of a cannula **122**. Cannula **122** has a second hollow body **124** that defines the second fluid passage **121**. Second hollow body **124** also has a pointed tip **125**. A pair of flanges **123** extend beyond cannula **122**, forming a saddle-shaped receiver **127** that partially surrounds the cannula. Receiver **127** is configured to slide over the sides of solution container **60**, receive a port on the solution container, and allow the port on the solution container to connect with cannula **122** in a secure arrangement.

Referring now to FIGS. **4-6**, **11**A and **11**B, valve body **132** features a cylindrical shaft **134** that extends into connector body **101**. Shaft **134** has a first end **134***a* that extends through one side of connector body **101** and a second end **134***b* that extends through the opposite side of the connector body. Shaft **134** is rotatable relative to connector body **101** on a control axis **136**. Third fluid passage **131** extends through the shaft perpendicularly to control axis **136**, as shown in FIG. **11**B. Third fluid passage **131** also defines a first opening **133** on a first side **135** of the shaft, and a second opening **137** on a second side **139** opposite the first side of the shaft. Shaft **134** includes a cylindrical shaft surface **138** that forms one part of a seal interface, as will be explained.

Control valve **130** includes a seal body **140** that cooperates with valve body **132** to control the flow of fluid through connector **100**. Seal body **140** defines a passage **142** having a passage wall **144**. Passages and passage walls according to the present disclosure can have various cross sectional geometries for sealingly engaging the seal body, including but not limited to regular polygonal, irregular polygonal, elliptical, oval and circular. In the present example, passage **142** has a circular cross section so as to form a cylindrical passage.

Referring to FIGS. **7-9**, passage **142** has a first passage end **142***a* and a second passage end **142***b* opposite the first passage end. Passage **142** also defines an inner diameter that varies between first passage end **142***a* and second passage end **142***b*. The inner diameter varies to form sections of reduced diameter that are configured to engage, wipe and form seals with shaft surface **138**, as will be explained. Shaft surface **138** slidingly engages passage wall **144** while maintaining a sealed interface with the passage wall. In this arrangement, seal body **140** surrounds shaft surface **138** and forms a seal interface between the seal body and shaft surface during movement of valve body **132**.

Seal body **140** defines a first aperture **151** and a first conduit **152**. First aperture **151** and first conduit **152** extend between cylindrical passage **142** and first flow passage **111**, as seen in FIG. **11**A. Seal body **140** also defines a second aperture **153** and a second conduit **154**. Second aperture **153** and second conduit **154** extend between cylindrical passage **142** and second flow passage **121**, as seen in FIG. **11**A. First conduit **152** includes a first tapered section **155** that expands radially outwardly and widens toward first aperture **151**. Second conduit **154** includes a second tapered section **156** that expands radially outwardly and widens toward second aperture **153**. First conduit **152** and second conduit **154** are axially aligned with one another and extend transversely to cylindrical passage **142**.

Referring to FIGS. **11**A-**13**B, shaft **134** is rotatable relative to seal body **140** and connector body **101** during operation of control valve **130**. Shaft **134** can be rotated ninety degrees between a first shaft position and second shaft position. In the first shaft position, third fluid passage **131** extends perpendicular to, and out of alignment with, first and second conduits **152**, **154** and first and second flow passages **111**, **121**. This position, shown in FIG. **11**A, places connector **100** in the closed state. In the second shaft position, third fluid passage **131** is parallel to and axially aligned with first and second conduits **152**, **154** and first and second flow passages **111**, **121**. This position, shown in FIG. **13**A, places connector **100** in the activated state. First flow passage **111**, first conduit **152**, third flow passage **131**, second conduit **154** and second flow passage **121** align end to end to create a singular and continuous linear flow passage through connector **100** when the connector is in the activated state. Seal body **140** is positioned in connector body **101** so that first conduit **152** is always axially aligned with first flow passage **111**, and second conduit **154** is always axially aligned with second flow passage **121**.

Connectors according to the present disclosure can feature one or more seal interfaces. The seal interface(s) prevent fluid flow between a drug vial and solution container when the connector is in the closed state. In addition, the seal interface(s) prevent unwanted flow of fluid within the connector when the connector is in either the closed state or activated state. For example, one or more seal interfaces can be provided between the valve body and seal body to limit or prevent seepage of fluid in spaces between the valve body and seal body. In addition, or in the alternative, one or more seal interfaces can be provided between the seal body and connector body to limit or prevent seepage of fluid in spaces between the seal body and connector body.

Referring back to FIGS. **7-9**, seal body **140** has four substantially planar sides **140***a*, **140***b*, **140***c*, **140***d*. Seal body **140** also has two tapered sides **140***e*, **140***f* arranged on opposite sides of the seal body. Each tapered side **140***e*, **140***f* tapers outwardly and away from cylindrical passage **142**, forming a V-shaped face. The V-shaped face of tapered side **140***e* forms a vertex along a midline **140***g*, and the V-shaped face of tapered side **140***f* forms a vertex along a midline **140***h* parallel to midline **140***g*. In this configuration, seal body **140** has a generally hexagonal cross section conforming to two trapezoids that intersect, as shown in FIG. **8**. This hexagonal cross sectional shape aids the insertion of seal

body **140** into connector body **101**, as will be explained. The hexagonal cross sectional shape also distributes compression loading more uniformly around shaft **134**.

Referring to FIGS. **12A-13B**, second coupling **120** is directly connected to first coupling **110** such that first outer wall **110***a* and second outer wall **120***a* form a first chamber **101***c* inside the first and second couplings. In addition, the pair of first chamber walls **104***a* and the pair of second chamber walls **104***b* form a second chamber **103** inside the first and second couplings that houses seal body **140**. Chamber **103** has an internal geometry that conforms to the outer geometry of seal body **140**. In particular, first chamber walls **104***a* and second chamber walls **104***b* have a V-shaped geometry conforming to tapered sides **140***e*, **140***f*. Seal body **140** is made of a resilient seal material such as silicone. The outer diameter of shaft surface **138** is slightly greater than the inner diameter of cylindrical passage **142**. In this arrangement, insertion of shaft **134** into cylindrical passage **142** during assembly pushes the walls of seal body **140** outwardly, expanding the seal body. This outer expansion causes seal body **140** to bear against first chamber walls **104***a* and second chamber walls **104***b* in chamber **103**, creating an outer seal around the seal body.

Referring again to FIGS. **7-9**, seal body **140** also forms outer seals around areas of chamber **103** that intersect with first and second flow passages **111**, **121**. In particular, planar sides **140***a*, **140***c* of seal body **140** each include a pair of concentric ring shaped seals **149**. Ring shaped seals **149** surround first and second apertures **151**, **153**, respectively. Each ring shaped seal **149** forms an outward protrusion or rib that contacts connector body **101**. In this arrangement, ring shaped seals **149** entrap fluid that seeps from the flow passages into areas between seal body **140** and connector body **101**, preventing that fluid from migrating beyond the ring shaped seals.

Seal body **140** further defines inner seals between passage wall **144** and shaft **134**. Some of the inner seals are arranged in a central portion **143** of cylindrical passage **142** that surrounds the third flow passage **131**, as shown in FIG. **9**. Other inner seals are arranged in cylindrical passage **142** outside of central portion **143**.

The inner seals include eight circumferential seals **146** on passage wall **144** in central portion **143**. Each circumferential seal **146** is a short, linear, inwardly extending protrusion or rib that extends parallel to control axis **136** and contacts shaft surface **138** in a sealing engagement. In this arrangement, circumferential seals **146** entrap fluid that seeps from first conduit **152** and/or second conduit **154** into the space between shaft surface **138** and passage wall **144**, preventing further flow of that fluid in a circumferential direction relative to control axis **136**.

The inner seals also include six axial seals **148** on passage wall **144** outside of central portion **143**. Three axial seals **148** are positioned on one side of third flow passage **131**, and the other three axial seals are positioned on the opposite side of the third flow passage. Each axial seal **148** is a ring-shaped, annular, inwardly extending protrusion or rib that circumscribes control axis **136** and contacts shaft surface **138** in a sealing engagement. In this arrangement, axial seals **148** entrap fluid that seeps between shaft surface **138** and passage wall **144** and prevents further flow of that fluid in an axial direction parallel to control axis **136**.

Seals according to the present disclosure can have different cross sectional shapes. Two options include trapezoidal shaped seals and rounded seals. Trapezoidal seals generally provide a better seal than rounded seals because they provide greater deflection with less compressive force to create the required pressure differential between seals. However, rounded seals undergo less damage than trapezoidal seals in instances where the seals rub against adjacent surfaces during assembly. This resistance to damage can outweigh the superior sealing properties of trapezoidal seals if the stresses on the seals are significant. Therefore, the specific shape of a seal can be selected based on factors such as its location and the stresses it is subjected to during assembly.

In the present example, ring shaped seals **149** are trapezoidal in cross section, as seen in FIGS. **8** and **9**. This shape provides more deflection of the seal with less compressive force to create the required pressure differential between the seals. Circumferential seals **146** and axial seals **148** have oval or elliptical shaped cross sections. These shapes are more rounded to allow insertion of shaft **134** into cylindrical passage **142** without causing damage to the seals. The oval or elliptical shapes of circumferential seals **146** and axial seals **148** also provide the largest possible sealing surfaces against shaft **134**.

Control valves according to the present disclosure are the mechanisms used to activate the connector. Once the connector is activated, the drug vial and solution container are connected in fluid communication, allowing mixing to take place. Connectors according to the present disclosure can include mechanisms to prevent accidental activation so as to avoid pre-mature mixing before the medication is needed. In addition, connectors according to the present disclosure can include mechanisms that inform users about the operative condition of the connector, i.e. whether the connector is closed or activated. Moreover, connectors according to the present disclosure can include mechanisms that allow users operating the control valve to know when they have successfully activated the connector. Finally, connectors according to the present disclosure can include mechanisms that prevent the connectors from being used more than once.

In the present example, connector **100** integrates the foregoing mechanisms into valve body **132** generally, and more specifically, into a control handle **160** as shown FIGS. **4-6**. Control handle **160**, which is part of valve body **132**, includes a circular dial **162** attached to first end **134***a* of shaft **134**. Dial **162** extends in a plane perpendicular to control axis **136**, and is centered on the control axis such that the center of the dial lies on the control axis. A first side **164** of dial faces away from connector body **101**, and a second side **166** of the dial faces toward connector body. A finger rest **168** projects outwardly from first side **164** and is configured to allow a user to rotate the dial using their fingers and/or thumbs in a twisting motion. Dial **162** can be rotated to rotate shaft **134** between the first and second shaft positions, thus moving the connector from the closed state to the activated state.

Control handles according to the present disclosure can have different configurations, and need not have circular dials. For example, control handles can also feature a polygonal shaped dial, a T-handle, a knurled knob, or other suitable structure for rotating the shaft.

Shaft **134** is inserted through two openings **102** in the walls of connector body **101**. In this position, shaft **134** is rotatable about control axis **136** but has limited ability to translate along control axis. Axial translation of shaft **134** through connector body **101** is limited by dial **162** on one side of the connector body and a pair of tapered flanges **180** on the opposite side of the connector body. Flanges **180** are configured to converge radially inwardly as second end **134***b* is inserted through each of the openings **102** in the wall of connector body **101**, and subsequently expand. Once expanded, flanges **180** are larger than openings **102**, pre-

venting shaft **134** from being reversed out of connector body **101**. This axial fixation of shaft **134** is shown in FIGS. **10**A-**13**B.

Referring to FIGS. **3**A-**4** and **6**, control handle **160** and connector body **101** feature rotation limiters that control how far dial **162** and shaft **134** can be rotated relative to the connector body. Control handle **160** has a first rotation limiter in the form of two stop pegs, pins or tabs **161**. One tab **161** is visible through the partial break in FIG. **3**A, with the other tab being diametrically opposed and shown in FIG. **6**. Connector body **101** has a second rotation limiter in the form of two arc-shaped tracks **105**. Each track **105** has a first end wall **106**, a second end wall **107**, and an arc-shaped pathway **108** extending between the first and second end walls. Each tab **161** is positioned in one of the tracks **105** and movable within its arc-shaped pathway **108** as dial **162** is rotated relative to connector body **101**. First and second end walls **106**, **107** provide stops that prevent tab **161** from moving beyond the end walls.

When looking at first side **164** of dial **162** in FIG. **3**A, the relative positions of tabs **161** in tracks **105** can be described in terms of numbers on a clock face. The counterclockwise direction is represented by the arrow CCW. For brevity, the relative position of the visible tab **161** will be described, with the understanding that the position of the other tab is offset by 6 hours on the clock face (i.e. 180 degrees) and moves in the same manner.

The visible tab **161** in FIG. **3**A is shown abutting first end wall **106** in the 6 o'clock position. In this position, shaft **134** is oriented in the first shaft position which places the connector in the closed state. The same tab **161** is shown in FIG. **3**B abutting second end wall **107** after the tab is rotated counterclockwise ninety degrees to the 3 o'clock position. In this position, shaft **134** is oriented in the second shaft position which places the connector in the activated state. Thus, each tab **161** is movable in its respective track **105** through a range of 90 degrees to move shaft **134** from the first shaft position to the second shaft position. Consequently, dial **162** can be rotated counterclockwise ninety degrees, starting from the first orientation shown in FIG. **3**A, and ending in the second orientation shown in FIG. **3**B, in order to switch connector **100** from the closed state to the activated state. To maintain the connector in the activated state, second end wall **107** stops tab **161** at the 3 o'clock position to prevent counterclockwise rotation of shaft **134** past the second shaft position.

Connector **100** has a one-way lock **170**, which is shown engaged in FIG. **10**B. The term "one-way lock", as used herein, refers to a mechanism that prevents relative movement of an object in one direction after the mechanism is engaged, but allows relative movement of the object in the opposite direction. In the present example, one-way lock **170** allows shaft **134** to rotate in the counterclockwise direction toward the second shaft position, but prevents the shaft from being rotated back toward the first shaft position after dial **162** is rotated counterclockwise past a certain point. This prevents connector **100** from being restored to the closed state after connector **100** is activated.

One-way lock **170** cooperates with other features of connector **100** to eventually form a two-way lock **175**. The term "two-way lock", as used herein, refers to a mechanism that prevents relative movement of an object in one direction after the mechanism is engaged, as well as relative movement of the object in the opposite direction. Two-way lock **175**, which is shown engaged in FIGS. **3**B and **10**C, is configured to retain connector **100** in the activated state after activation to prevent the connector from being reused.

Referring to FIGS. **6** and **10**A, one-way lock **170** includes two pairs of ratchet teeth or ramps arranged around second side **166** of dial **162**. One-way lock **170** also includes two ledges **109** on the exterior of connector body **101** that engage the ramps. Each pair of ramps includes a first ramp **171** and a second ramp **172**. First and second ramps **171**, **172** project from second side **166** of dial **162** and are configured to engage ledges **109** on the exterior of connector body **101**. One of the ledges **109** is shown in FIG. **10**A. Each ledge **109** extends toward second side **166** of dial **162** in a position to positively engage first and second ramps **171**, **172** when the dial is rotated. Each of ramps **171**, **172** has a leading edge **173** and a trailing edge **174**. Each leading edge **173** has a sloped surface, with the slope defined by an acute angle between the sloped surface and second side **166** of dial. Each trailing edge **174** extends normal to second side **166**. First and second ramps **171**, **172** are arranged on dial **162** so that their leading edges **173** are the first edges to engage ledge **109** during counterclockwise rotation.

Connectors according to the present disclosure can include removable caps that cover the first and second couplings. The removable caps can be configured to enclose the vial spike and cannula and protect them from contaminants. The removable caps can also allow users to hold the connector without placing their fingers near the vial spike and cannula, reducing the risk of injury from contact with the vial spike and cannula. Furthermore, the removable caps allow users to keep the vial spike and cannula covered, and delay exposing them until the moment before they are attached to drug vials and solution containers. Thus reduces the risk of the vial spike and cannula becoming contaminated before use.

Referring to FIG. **4**, connector **100** includes a first cap **117** that is attachable over and removable from vial spike **112**. Connector **100** also includes a second cap **119** that is attachable over and removable from second coupling **120**. First and second caps **117**, **119** can attach to vial spike **112** and second coupling **120**, respectively, by any suitable mechanism, such as mating surfaces on the exterior of the connector and interior of the cap that releasably engage. Suitable examples include but are not limited to tabs, detents, threading and other connections.

Referring to FIG. **11**A, connector **100** can be assembled in the following manner. Connector body **101** is made up of two separate halves, a first half **101***a* that includes first coupling **110**, and a second half **101***b* that includes second coupling **120**. First cap **117** is connected over vial spike **112** on first half **101***a*, and second cap **119** is connected over second coupling **120** on second half **101***b*. Seal body **140** is inserted into first half **101***a*, in an area that constitutes one part of chamber **103**. The tapered shape of seal body **140** and first chamber walls **104***a* aid in properly orienting and seating the seal body into first half **101***a*. Once the seal body **140** is seated in first half **101***a*, second half **101***b* is connected to the first half over the seal body. This applies compression force around seal body **140**.

Once connector body **101** is assembled, valve body **132** can be connected to the connector body. This is done by inserting second shaft end **134***b* of shaft **134** through openings **102** of connector body **101** and through cylindrical passage **142** of seal body **140**. Inserting shaft **134** through connector body **101** after the first and second halves **101***a*, **101***b* are connected provides more flexibility and latitude to obtain the required forces and/or ultrasonic energy required to create a robust, functional and secure assembly.

Once shaft **134** advances through both sides of connector body **101**, flanges **180** snap outwardly. Dial **162** and flanges

180 engage opposite sides of connector body 101 to lock the axial position of shaft 134 in the connector body. Insertion of shaft 134 through seal body 140 expands the seal body, thereby compressing the exterior of the seal body against first chamber walls 104*a* and second chamber walls 104*b* of chamber 103 to form a tight seal around the seal body.

A method of using a connector according to the present disclosure will now be described with reference to steps illustrated in FIG. 14 and using connector 100 as an example.

Connector 100 is removed from any packaging and inspected prior to use (step 1000). In particular, connector should be inspected to confirm that the connector is in the closed state. If connector 100 is not in the closed state, the connector should not be used. The operative state of the connector is indicated by the relative orientation of dial 162. The relative orientation of dial 162 can be determined by observing the orientation of finger rest 168 relative to vial spike 112 and cannula 122. Finger rest 168 should be oriented horizontally when cannula 122 is pointed upwardly, as shown in FIG. 3A. In this position, shaft 134 is oriented in the first shaft position so that third fluid passage 131 is perpendicular to, and therefore out of fluid communication with, first and second flow passages 111, 121. This condition is shown in FIGS. 11A and 11B. First and second flow passages 111, 121 are sealed off from one another by seal body 140, preventing any transfer of fluid from solution container 60 to drug vial 50, and vice versa.

Once the closed state is confirmed, connector 100 is connected to drug vial 50 (step 1100). Drug vial 50 is prepared for use according to the manufacturer's instructions. For example, if drug vial 50 has a protective cap over the stopper, the cap can be removed and the stopper can be disinfected using institutional protocol. Drug vial 50 is then placed on a hard flat surface in an upright position with the stopper facing up.

First cap 117 is carefully removed from connector 100 to expose vial spike 112. Second cap 119 remains attached over cannula 122. Connector 100 is held above drug vial 50 with vial spike 112 facing downwardly and aligned with the drug vial's stopper. Connector 100 is then lowered over drug vial 50, with one hand holding the drug vial stable on the flat surface, and the other hand gripping second cap 119. Connector 100 is lowered until the top of drug vial 50 enters socket 118, and tip 115 contacts the stopper. Referring to FIG. 4, second cap 119 includes a cylindrical handle portion 119*a* with surface splines 119*b* that make the second cap easier to grip during this process. Second cap 119 also has a flat end 119*c* that provides a place for the user to rest their palm.

Using their palm, the user presses straight down on flat end 119*c* of second cap 119 to push connector 100 onto drug vial 50. Connector 100 is pressed down firmly until vial spike 112 penetrates through the stopper and tip 115 enters the inside of drug vial 50. At this stage, drug vial 50 is held firmly between tabs 113, with the tabs preventing lateral movement of the drug vial.

With drug vial 50 now attached, connector 100 is connected to solution container 60 (step 1200). Second cap 119 is removed from second coupling 120 to expose cannula 122. A large flange 119*d* is provided on second cap 119 that allows the user to apply twisting or pulling force to remove the second cap from second coupling 120. Solution container 60 can be prepared for connection to cannula 122 according to instructions provided by the container's manufacturer. For example, if solution container 60 has a protective cap over the port, the cap is removed. The port is then disinfected using the appropriate protocol.

Solution container 60 is grasped in one hand, and connector 100 is held in the other hand with second coupling 120 facing the port on the solution container. Connector 100 can be held by grasping connector body 101 and/or the bottom of drug vial 50, the latter of which is exposed outside of the connector as shown in FIG. 1. Connector 100 is then advanced toward solution container 60, or vice versa, until the port on the solution container begins to enter receiver 127. Connector 100 is also rotated until flanges 123 are oriented relative to solution container 60 so they can slide over the sides of the solution container. Once flanges 123 are properly oriented, connector 100 is pushed onto solution container 60 until tip 125 of cannula 122 penetrates the port and enters the interior of the solution container. Care should be taken not to squeeze or apply compression force to solution container 60 at any time during assembly.

Drug vial 50, solution container 60, and connector 100 are now attached to one another for form set 20. Set 20 can be stored according to institutional protocol in a ready-to-mix condition, with the contents of vial 50 and solution container 60 sealed from one another. Control valve 130 remains closed during storage and transport to keep diluent 61 from contacting drug 51, even if set 20 is subjected to compression, vibration, shock or other form of agitation.

When the medication is needed, set 20 can be removed from storage and inspected prior to use (step 1300). Connector 100 should be visually inspected to confirm that the connector has remained in the closed state during storage. As noted above, the operative state of the connector is confirmed by observing the orientation of dial 162 and finger rest 168, the latter of which should appear in the horizontal orientation shown in FIG. 3A.

In addition to inspecting connector 100, drug vial 50 and solution container 60 should be visually inspected to identify any evidence of leakage of drug 51 and/or diluent 61, and/or mixing of the drug with diluent. If there is any evidence of leakage or mixing, set 20 should be discarded. If no concerns are found, the medication can be prepared.

To mix the contents of drug vial 50 and solution container 60, the user activates connector 100 (step 1400). From the vantage point represented in FIG. 3A, connector 100 is activated by rotating dial 162 in the counterclockwise direction. Connector 100 has multiple features that indicate the correct direction of rotation in the event that the user forgets or is unsure of which direction to turn the dial. First, dial 162 includes visual indicia 167 on first side 164 of dial 162, as shown in FIG. 5. Indicia 167 consists of a written instruction and arrows indicating that the dial should be rotated counterclockwise to activate connector 100.

Connector 100 also provides tactile feedback that informs the user of the correct direction of rotation. Tactile feedback is provided by the initial engagement between tabs 161 and first end walls 106 in tracks 105. First end walls 106 abut tabs 161 to prevent the tabs from moving in a clockwise direction with respect to FIG. 3A. This creates physical resistance to clockwise rotation, which the user feels through their fingers when attempting to rotate dial 162 clockwise from the closed position.

As the user rotates dial 162 counterclockwise, tabs 161 begin moving in a counterclockwise direction along tracks 105. Shaft 134 also begins rotating counterclockwise relative to seal body 140. In particular, shaft 134 rotates out of the first shaft position and toward the second shaft position. This gradually rotates third fluid passage 131 into alignment with first and second fluid passages 111, 121. Dial 162 is

rotated counterclockwise until first ramps **171** contact their corresponding ledges **109**. As each first ramp **171** contacts its respective ledge **109**, the user can detect a slight resistance to further rotation in their fingers. This resistance is caused by interference between ledges **109** and the sloped surfaces of leading edges **173**. FIG. **10**A shows dial **162** rotated counterclockwise with one of the ledges **109** interfering with one of the first ramps **171**. The other first ramp **171** and ledge **109** are also engaged in the same manner on the opposite side of dial **162**. In this state, dial **162** is deflected outwardly under stored energy in response to contact between first ramps **171** and ledges **109**.

Dial **162** is rotated counterclockwise until the trailing edges **174** of first ramps **171** pass ledges **109**. When the trailing edges **174** rotate past ledges **109**, dial **162** reaches an intermediate position, indicating that connector **100** is partially activated. The term "partially activated", as used herein, refers to an operative state between the closed state and the activated state. First and second flow passages **111**, **121** are still sealed from one another by seal body **140** to prevent transfer of fluid from drug vial **50** to solution container **60**, and vice versa. However, third fluid passage **131** is rotated closer to alignment with first flow passage **111** and second flow passage **121**. The partially activated state is shown in FIGS. **12**A and **12**B.

When dial **162** reaches the intermediate position, ledges **109** no longer interfere with first ramps **171**. Therefore, the forces causing deflection of dial **162** are removed, allowing the stored energy in the dial to release and return the dial to its relaxed state. Dial **162** snaps back to its relaxed form, creating an audible click that the user hears. In addition, the user detects the disengagement of first ramps **171** from ledges **109** through tactile feel, as the resistance to counterclockwise rotation felt through finger rest **168** drops substantially. As such, the user feels greater and greater resistance to counterclockwise rotation as dial **162** approaches the intermediate position, followed by a sudden drop in resistance when the dial reaches the intermediate position. Finger rest **168** is oriented at an acute angle relative to its original horizontal orientation. This change in appearance of finger rest **168** allows the user to infer their progress as they rotate dial **162** toward the activated condition.

Each ledge **109** creates an obstruction in the path of each trailing edge **174** after dial **162** reaches the intermediate position. Each trailing edge **174** extends normal to second side **166**, as noted above, such that it will abut its respective ledge **109** if the user attempts to rotate dial **162** clockwise from the intermediate position. As such, first ramps **171** and ledges **109** form a one-way lock **170**, as mentioned earlier. One-way lock **170** prevents rotation of dial **162** clockwise from the intermediate position, while allowing continued counterclockwise rotation of the dial from the intermediate position. The abutment between one of the trailing edges **174** and its corresponding ledge **109** is shown in FIG. **10**B.

Dial **162** is rotated counterclockwise from the intermediate position until second ramps **172** engage ledges **109**. Second ramps **172** are configured to engage and pass ledges **109** in the same manner as first ramps **171**. That is, dial **162** deflects to a stored energy condition and snaps back to a relaxed condition in the same or similar manner as when first ramps **171** engage and pass ledges **109**. When the trailing edges **174** of second ramps **172** pass ledges **109**, dial **162** has reached a final position, shown in FIG. **3**B. In this state, shaft **134** is oriented in the second shaft position shown in FIGS. **13**A and **13**B, which places connector **100** in the activated state.

The activated state is signaled to the user in a manner similar to the partially activated state. Dial **162** snaps back to its relaxed form, creating an audible click that the user hears. In addition, the user can detect the disengagement of second ramps **171** from ledges **109** through tactile feel as dial **162** snaps back to its relaxed form. However, the user also notices that dial **162** has little or no ability to rotate in either the clockwise or counterclockwise direction relative to connector body **101**. Clockwise rotation is limited by ledges **109**, which obstruct the paths of second ramps **172** to limit or prevent clockwise rotation of dial **162**. The obstruction created by one of the ledges **109** in the path of one of the second ramps **172** is shown in FIG. **10**C.

Further rotation of dial **162** in the counterclockwise direction is also prevented by the abutment between tabs **161** and second end walls **107** of tracks **105**. This abutment, shown in FIG. **3**B, prevents shaft **134** from rotating past the second shaft position, which would rotate third flow passage **131** past its aligned orientation with first and second flow passages **111**, **121**. In this arrangement, second ramps **172**, ledges **109**, tabs **161** and second end walls **107** form the two-way lock **175** mentioned earlier. Two-way lock **175**, which is represented in FIGS. **3**B and **10**C, prevents dial **162** from rotating in either direction after it reaches its final position. Therefore, rotation of dial **162** from the intermediate position to the final position passively locks connector **100** in the activated state (step **1500**).

Once connector **100** is activated and locked in the activated state, the user can prepare the medication by mixing the contents of drug vial **50** and solution container **60** through the connector (step **1600**). This may include steps such as folding and/or squeezing solution container **60** to cause diluent **61** to flow through connector **100** into drug vial **50** to mix with drug **51** and return to the solution container.

The foregoing steps do not apply exclusively to connector **100**, and can be performed with other connectors according to the present disclosure.

Although this description makes reference to specific embodiments and illustrations, the present disclosure is not intended to be limited to the details shown. Rather, the present disclosure encompasses various modifications and combinations of embodiments and features described herein, as well as other variations that may be made within the scope and range of the claims and equivalents.

For example, in another exemplary embodiment, the connector could be activated by rotating the dial in a clockwise direction relative to FIG. **3**A, rather than counterclockwise. In addition, the dial can feature more ramps on the dial to provide one-way locks at two or more intermediate positions. As an alternative, the dial can have only one ramp on each half of the dial, so that the dial is only lockable in the final position corresponding to the activated state. In such an arrangement, the dial would only be locked via a two-way lock.

Connectors according to the present disclosure can also connect containers at various angles other than the angle shown in FIGS. **1** and **2**. For example, it may be desirable in some applications to connect a first fluid container with a second fluid container at a slight angle so that one of the containers is raised or tilted. In such an application, a connector may feature a first coupling and a second coupling angularly offset from the first coupling by an obtuse angle, for example 150 degrees, so that the second flow passage is offset from the first flow passage by 150 degrees. In another application, the connector can have first and second flow passages oriented in an L-shape, i.e. offset 90 degrees from one another. The third flow passage through seal body could

be bent or curved at one or more sections to accommodate any angular offset between containers and any change in flow direction between the first and second flow passages.

Accordingly, it is intended that the appended claims cover all such variations as fall within the scope of the present disclosure.

What is claimed:

1. A connector for fluidly connecting a drug container with a solution container in a closed state, and for combining contents of the drug container and the solution container in an activated state, the connector comprising:

a connector body comprising:

a first coupling for fluid connection with the drug container, the first coupling having a first outer wall defining a first fluid passage and a pair of first chamber walls;

a second coupling for fluid connection with the solution container, the second coupling having a second outer wall defining a second fluid passage and a pair of second chamber walls,

the second coupling directly connected to the first coupling wherein the first outer wall and the second outer wall form a first chamber inside the connected first and second couplings and the pair of first chamber walls and the pair of second chamber walls form a second chamber inside the connected first and second couplings;

a seal body contained within the second chamber, the seal body comprising a first portion housed between the pair of first chamber walls in the first coupling and a second portion housed between the pair of second chamber walls in the second coupling; and

a movable valve body defining a third fluid passage and extending through the seal body contained in the second chamber in the connected first and second couplings, the movable valve body rotatable relative to the connector body in a first position, in which the first fluid passage is sealed from the second fluid passage to place the connector in the closed state, and rotatable relative to the connector body in a second position, in which the first fluid passage is connected in fluid communication with the second fluid passage by the third fluid passage to place the connector in the activated state.

2. The connector according to claim **1**, wherein the second chamber is formed within the first chamber.

3. The connector according to claim **1**, wherein the first fluid passage extends parallel to the second fluid passage.

4. The connector according to claim **1**, wherein the seal body comprises first and second sides on opposing sides of the seal body, and wherein the first side of the seal body and the second side of the seal body are tapered outwardly and away from the movable valve body extending through the seal body.

5. The connector according to claim **4**, wherein the seal body further comprises third and fourth sides formed on opposing sides of the seal body and arranged transverse relative to the first and second sides of the seal body, the third side of the seal body having a first aperture in fluid communication with the first fluid passage and the fourth side of the seal body having a second aperture in fluid communication with the second fluid passage.

6. The connector according to claim **5**, wherein the first aperture and the second aperture are diametrically opposite each other.

7. The connector according to claim **1**, wherein the third fluid passage extends transversely relative to the first and second fluid passages.

8. The connector according to claim **1**, wherein the seal body defines a seal body passage having a passage wall that slidingly engages an outer surface of the movable valve body and comprises an annular seal which forms a seal interface between the seal body and the outer surface of the movable valve body.

9. The connector according to claim **8**, wherein the seal body passage comprises a first passage end, a second passage end, and an inner diameter that varies between the first passage end and second passage end and forms one or more sections of reduced diameter configured to engage, wipe and form one or more seals with the outer surface of the movable valve body.

10. The connector according to claim **5**, wherein the seal body further comprises an exterior surface having at least one sealing rib around the first aperture and at least one sealing rib around the second aperture.

11. The connector according to claim **4**, wherein the pair of first chamber walls and the pair of second chamber walls are configured to conform to the tapered first and second sides of the seal body.

12. The connector according to claim **1**, further comprising at least one aperture defined in the first outer wall of the first coupling, wherein the movable valve body extends through the at least aperture defined in the first outer wall of the first coupling and through the seal body.

13. The connector according claim **5**, wherein the third fluid passage is aligned with the first and second apertures of the seal body when the movable valve body is in the activated state.

14. The connector according to claim **13**, wherein the third fluid passage is rotated out of alignment with at least one of the first and second apertures of the seal body when the movable valve body is in the closed state.

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